"Assessment of Right Heart functions and dimensions following device closure of Atrial Septal Defect"

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CERTIFICATE

This is to certify that the dissertation titled "**Assessment of Right Heart function and dimensions following device closure of Atrial Septal Defect"** is the bonafide original work of **Dr.J.Cecily Mary Majella** in partial fulfillment of the requirements for D.M. Branch-II (CARDIOLOGY) examination of THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY to be held in August 2014. The period of post-graduate study and training was from August 2011 to July 2014.

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DECLARATION

I, **Dr.,J.Cecily Mary Majella** solemnly declare that this dissertation entitled, "**Assessment of Right Heart function and dimensions following device closure of Atrial Septal Defect**" is a bonafide work done by me at the department of Cardiology, Madras Medical College and Government General Hospital during the period 2011 – 2014 under the guidance and supervision of the Professor and Head of the department of Cardiology of Madras Medical College and Government General Hospital, Professor M.S.RAVI , M.D., D.M., This dissertation is submitted to The Tamil Nadu Dr. M.G.R Medical University, towards partial fulfillment of requirement for the award of **D.M. Degree (Branch-II) in Cardiology**.

Place: **SIGNATURE OF THE CANDIDATE**

Date:

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CONTENTS

INTRODUCTION

Atrial septal defect (ASD) represents one among the most common congenital heart disease manifested in adult life. It accounts 7% to 10% of all congenital heart disease in children. Ostium secundum being the most predominant type and common among females often comes to light in young adults[1].[20]

Most of the infants and children presenting with ASD remain asymptomatic and clinical examination may be unimpressive, making their survival to adulthood as normal as others. The right heart is exposed to chronic volume overload due to an increased pulmonary flow which leads to dilatation of the right atrium and right ventricle (RV)[1][21]. Some patients might progress to various stages of pulmonary hypertension and right sided heart failure. Patients may manifest with dyspnoea, fatigue, recurrent lower respiratory tract infection, arrhythmias, and thromboembolic complications. There has been consensus by the American Heart Association and European society of cardiology that complete closure of the inter atrial communication is the management of choice for ASD with significant pulmonary to systemic flow ratio, particularly in the presence of right ventricular

volume overload along with right atrial and right ventricular dilatation, even if the patient has few or no symptoms.

Patients who come to medical attention with isolated secundum atrial septal defects (ASDs) really benefit from the recent advances in optimising the diagnosis, and management[13,14,23]. My work will mainly focus on adolescents and adult subgroup of patients with optimal sized ASDs who do not have other major associated anomalies.

The Himalayan progress in the field of interventional cardiology has led to the birth of percutaneous device closure of secundum ASD. This approach is feasible in around 60–70% of individuals depending on the site, and size of defect, the adequacy [at least 5 mm] of all the five rims [antero inferior, postero superior, inferior vena caval, superior vena caval and aortic rims] and the patient's presenting age[22]. The Amplatzer septal occluder device has been in use since its inception in 1995[25]. After undergoing various multicentre randomized clinical trials, the device was authenticated and approved by United States of America Food and Drug Administration bureau (FDA) in 2002 for use both in children and the adult subgroup. For percutaneous transcatheter closure secundum defects using Amplatzer septal occluder, added criteria include that the defect size is not large for the currently available occluder devices, and ideal

distance should prevail so that the device does not encroach the vital surrounding structures such as the aorta ,coronary sinus, right upper pulmonary vein ,conduction system and atrioventricular valves .The main contraindications for this percutaneous method of device closure of secundum defects include very large defects not amenable for closure or smaller and floppy rims (exception being the anterosuperior rim of aorta).Infants who are symptomatic are usually corrected surgically. However, this novel percutaneous method has been successfully implemented even in children who weigh 10 kg or less [,34]. Those who are not ideal candidates for device closure is referred for pericardial patch closure of the septal defects which is done with optimal results in subjects from infancy to even late adulthood, though it may lead to morbidity, and a disfiguring thoracotomy scar [33].

Right atrial and right ventricular volume overload[42,43,44] are well documented consequences of unrepaired atrial septal defects. Persistent shunting across the defects, manifesting as right heart enlargement and dilatation, may progress to symptomatic disabling arrhythmias.

The main of purpose of this study is to assess the right ventricular and right atrial size and function and the time they take to normalize after

percutaneous device closure of ostium secundum atrial septal defect with appropriate sized septal occluder[55].

During the recent years percutaneous closure of secundum type inter atrial defects were first implemented in clinical practice and was, next to or at par to surgical procedure, a secure, quite efficient, and scar free option for inter atrial defect closure. Some studies [8,10] comparing transcatheter closure versus surgical closure of septum secundum defects, the percutaneous transcatheter option proved superior[35,36]. Myocardial function evaluation[60], systolic as well as diastolic, was found to be impaired by open surgical technique but well preserved after percutaneous transcatheter closure. There exists conflicting data on the clinical consequences after closure of septal defects as whether they actually improve right ventricular function and performance or just prevent further deterioration[59]. I would quote Eidem *et al* [11][57] who initially described no significant alteration in right ventricular function in patients after surgical closure of inter-atrial septal defects. But, Salehian *et al*[14][58] reported that transcatheter closure of atrial septal defect led to improvement of biventricular function. Divergent results may suggest that the differences could be due to various closure techniques that are being opted and interpatient variabilities[56].

Therefore we analyzed the pre and post procedure dimensions and function of right heart and closely monitored them immediately in the post procedure period and followed them at one week, one month, 3 months after the procedure and also compared them with the surgical closure results.

AIMS & OBJECTIVES

To assess right heart function, right atrial and right ventricular dimensions pre and post transcatheter closure of atrial septal defect (ASD) and to assess magnitude of resolution of right heart enlargement, and impact on right ventricular function by echocardiography using 2D and tissue Doppler imaging.

To compare the final outcomes after 3 months of percutaneous transcatheter closure of atrial septal defect with that of surgical closure.

REVIEW OF LITERATURE

INTRODUCTION:

Leonardo da Vinci wrote, “I’ve found from the left atrium to right atrium a perforating channel”. His contribution to true interatrial septal defect is known to be the first human record on congenital defects.[1] Atrial septal defect comprises about 5-10% of all congenital heart diseases. It ranks first among the acyanotic congenital heart disease presenting in adulthood. Since the clinical presentation and physical manifestations are mostly subtle it may go unrecognized and come to limelight only in late adulthood. Though in most of the patients survival into adult life may be the rule of the day, both quality and expectancy of life is impaired in unintervened atrial septal defects, because of the longterm impact of volume overload on the right heart geometry and function. With expertise, skill, and hardwares constantly improving day by day, ASD device closure has now become the foremost mode of treatment option for patients with ostium secundum-ASD. However the defect size and morphology, and adequacy of rims still remains the primary determinant and key to most successful device closure of atrial septal defect.

ANATOMY AND DEVELOPMENT OF INTERATRIAL SEPTUM:

During early development**,** the heart initially starts of as a single atrium. Septum primum normally grows from the atrial roof towards the endocardial cushions those results in closure of Foramen primum shunt. Foramen secundum is the perforation or fenestration in the middle of the thin septum primum, allowing shunt from right to left in fetal life. Septum secundum grows down on the right side overlapping the foramen secundum. Septum secundum is a crescentic shaped muscular membrane arising from ventro-cranial wall of the atrium. Foramen Ovale is guarded by the valve of foramen ovale (Septum primum), which normally closes functionally by 24 hours, and anatomically by 72 hours. The closure is due to the drop in lung pressures after birth and the exceeding pressure in the left atrium than that of the right atrium that results in opposition of the septum and sealing of defect completely in upto three fourths of the infants. The fossa ovalis is as of a saucer shaped depression in the floor of septum primum. The limbus of the fossa ovalis is formed from the inferior most edge of septum secundum. They occupy 28% of the septal area. The interatrial septum when viewed from the right side is like a blade in shape and structure with an anterosuperior rim that reflects the ascending aortic curvature, mitral annulus which forms the inferior

margin, and a convex posterior margin. The left aspect of septum has trabecular network which are remnants of primum septum.

Interatrial septal aneurysm is due to redundancy of the valve of the foramen. These septal aneurysms which represent congenital outpouching close to the fossa ovalis may perforate at times resulting in left to right shunting. Atrial septal aneurysms constitute approximately 10% of individuals undergoing transthoracic echocardiography and around 30% of individuals presenting with cryptogenic stroke associated with a patency of foramen ovale.The incidence of persistent patency of the foramen of ovale ranges from 30-35% during the initial three decades of life and declines to 25% from 30-70 years of age. In general, the foramen ovale which is patent may result in a right to left and not from left to right shunting as occurs when the pressure in right sided atrium exceeds that of left as during the strain phase of Valsalva's maneuver or during general straining.

CLASSIFICATION OF ATRIAL SEPTAL DEFECTS:

Secundum defect:

Being the most common variety constitutes 70-80%. It could be single, or multiple, and may be oval rather than circular in shape. Their anatomy is seemingly more complex on the right aspect rather than the

left of the septum. These defects are apparently due to deficiency in the growth of secundum septum, excessive shortening of foramen ovale valve, and lastly due to undue resorption of primum septum. Swiss cheese pattern represent multiple small defects usually less than 5 mm. The prevalence is twice more common among the female gender more than the males. Usually a single defect is present but in 10% of individuals more than one defect is present. Approximately, one third of individuals may have mitral valve prolapse, or associated congenital malformations as pulmonary stenosis, sub aortic stenosis, ventricular septal defects, anomalous pulmonary venous drainage in 10%, and coarctation of aorta. It can also be associated with acquired heart disease as rheumatic mitral stenosis well known by all as the Lutembacher syndrome. Controversy exists as whether this syndrome represents only mitral stenosis or it can also be associated with acquired mitral regurgitation.

Primum defect:

It comprises 15-20% of the atrial septal defects which involves the lower portion of the interatrial septum and typically involves the ventricular septum as well as the so called atrio-ventricular canal defect. Oddly and very rarely when septal structures remain intact continuity exists in the atrioventricular septum. Both the atrio-ventricular valves are

structurally abnormal and the mitral valve is typically cleft giving rise to mitral regurgitation of varying degrees. The gender ratio is approximately equal in ostium primum type of ASD. The terminology ostium primum does not necessarily characterize the interatrial defect since it is not a defect in the interatrial septum, but rather is absence of the atrio-ventricular septum.

Depending on the arrangement and attachment of the bridging leaflets the shunt exists at the atrial or ventricular level and when the bridging leaflets are not attached to any portion and floating freely resulting in shunt both at the atrial and ventricular levels an arrangement called as the complete common atrio-ventricular canal. Due to posterior displacement of the penetrating bundle which lies in the postero–inferior rim of the ventricular component of the defect and the variation in the length and activation of the anterior and posterior fascicles explains the electro physiologic abnormalities like extreme to moderate left axis deviation in these patients.[1,17] These defects are encountered commonly in Down syndrome [trisomy 21] and they present frequently early in life unlike the septum secundum defects due to their impact on the cardiovascular physiology developing congestive cardiac failure earlier and even hydrops fetalis. The chief determining factor is the severity of left atrio-ventricular regurgitation that may result in a mortality rate of

33% within the first year of life. Intractable heart failure may result from a hypoplastic left ventricle. Survival into adulthood could be expected only in the presence of a competent left atrio-ventricular valve.

Sinus venosus type of atrial septal defect:

These defects are not rare but uncommon and account for 3-5 %.These defects are positioned just beneath the superior vena cava and the right atrial junction and may range from small defects to non-restrictive form. The superior vena caval ostium can over-ride the septal defect and may be biatrial. This defect is almost always around 90% associated with partial anomalous pulmonary venous return, usually the right upper pulmonary vein or both of the right pulmonary veins draining into the right atrium. Because of this location the defect could be missed on a trans-thoracic echocardiography, and may require trans-esophageal echo imaging for proper delineation of the defect.

Inferior Vena Canal Defect:

This is one of the rare forms of Sino-septal defects, which poses difficulty in diagnosis and usually missed by trans –thoracic echo and may require trans-esophageal echo, or advanced imaging as computed tomography or magnetic resonance imaging.[15,16,21,23]

Unroofed coronary sinus:

This least form of atrial septal defect is associated with unroofed of coronary sinus, leading to shunting of left atrial blood to right atrium. It is usually associated with persistent left superior vena cava and anomalous pulmonary venous return which could be partial or complete.

Rims of an Atrial septal defect which are important is assessment of suitability of procedure:

Antero superior or (aortic rim)

Antero inferior or (atrio ventricular valve rim)

Coronary sinus rim

Infero posterior (inferior vena caval rim)

Postero superior or (pulmonary vein rim)

Superior Vena Caval rim

Ten morphological variations:

- Aortic rim Deficiency (42.1%).
- Central deficiency - (24.2%).
- Inferoposterior rim deficiency (12.1%).

- Septal Aneurysm Perforation (7.9%).
- Multiple defects (7.3%).
- Deficiency of both mitral and aortic rims (4.1%).
- Deficiency of Superior Vena Caval rim (1%) and deficiency of coronary sinus rim (1%).

-Ponder et al

Inter Atrial Septal Aneursym:

If there is excessive tissue in the septum primum and is also very weak, and floppy with a maximal mobility or excursion into the atria by more than 15 millimeters it is consistent with the diagnosis of septal aneurysm of the atrium.[26] Less than 15 millimeters excursion is named as – Redundant atrial septum. These aneurysms may coexist with either an ostium secundum defect or a patent foramen ovale which by incidence in most of the published series is around 60%, making its association relatively more common. Recurrent neurological events like transient ischemic attack or stroke is more likely to be linked with septal aneurysms coexistent with a shunt across the atrial septum.

PATHOPHYSIOLOGY:

The size of the defect is the key determinant for both the magnitude as well as the direction of flow through any septal defects. The biventricular compliance is also contributory to these shunts. Conditions which alter compliance of the left ventricle such as associated conditions like mitral stenosis, or hypertrophy of the ventricle may increase the shunt from left → right. Alternatively conditions that alters the compliance of the right ventricle like tricuspid stenosis, pulmonary stenosis ,and pulmonary hypertension which may result in elevated right heart pressures will have opposing hemodynamic effect of impeding the left → right shunting and when supersedes causes reversal of the shunt.

An ostium secundum defect must be a minimum of at least 10 mm diameter as a dictum to produce a hemodynamically significant shunt. The interatrial septum is a complex structure and hence not all septal defects are circular making the possibility of accurately measuring the defect size a cumbersome issue, and thus posing a real challenge to the skill of the percutaneous device closure operators who neither visualize the septum directly in comparison with the surgical closure technique where the operator has the ease of visualizing the septum directly.

A significant left→right shunt is diagnosed when the Qp/Qs ratio is more or higher than 1.5/1.0, or it imposes volume overload on the right heart leading to dilation of the right heart and impair the long-term prognosis.

CLINICAL FEATURES:

Symptoms are usually subtle in most of the patients, though they come to limelight at a particular point of time. The age of presentation is a highly indeterminate one and is not attributable entirely to the size of the defect alone. Most commonly the individuals present with dyspnea on exertion and effort intolerance and easy fatiguability. The chronology of the shunt is reflected by the dilated atria that may be a forerunner of arrhythmias such as atrial flutter or fibrillation, whose onset has a rapid deteriorating effect on the presenting symptoms. Adults may present with tricuspid regurgitation and pulmonary hypertension of varying degrees progressing to right heart dilatation and failure. A transient ischemic attack or an overt stroke may suddenly complicate the clinical scenario due to a paradoxical embolism.[6]

DIAGNOSTIC EVALUATION:

Clinical Examination:

Even though there is a day to day progress in the field of advanced diagnostic radiographic tools like MRI, many a time an accurate diagnosis is missed due to lack of the dying art of detailed history taking and clinical examination which still remains the golden key to unravel the diagnosis. Therefore a step wise approach still remains pertinent in every single patient. But, of course paucity or absence of clinical findings does not rule out a hemodynamically significant atrial septal defect. Hence both clinical and radiological evaluation should go hand in hand and complement each other.

Physical examination may reveal a palpable pulmonary artery pulsation, right ventricular parasternal heave or lift, fixed wide split due to absence of the differential effects of filling pressures of both sides during normal inspiratory fall of intrathoracic pressure.[18] A loud pulmonary component of second heart sound may not always be due to pulmonary hypertension but may also reflect the increased flow across the dilated pulmonary vascular tree which may also produce a systolic murmur, and a flow diastolic murmur across the tricuspid valve.

"*Crochetage sign"* initially described in 1996 by Heller is the characteristic notching observed in apical aspect of R wave in the inferior leads resembling the hook of a knitting needle may be present most commonly with secundum defects, patent foramen ovale and sinus venosus variety of defects. This sign may be present in 30% of ASD patients and may reflect the magnitude of shunt with 70% sensitivity and 90% specificity. The association of this sign with a PFO could be a forerunner of impending TIA or stroke. The sensitivity and specificity are reportedly high when associated with incomplete RBBB. This sign reverts or normalizes in 36% of individuals after closure of the defects.

Role of Echocardiography in ASD:

- Precise information in the vast majority
- Needs to be thorough and systematic
- Size of the defect
- Type of location of ASD
- Number of ASD's
- Right heart and left heart dimensions
- Right heart and left heart functions
- Direction of shunt
- MPA and branch pulmonary artery dimensions and PHT assessment and severity.[19]
- Assessment of associated valvular defects
- Assessment of associated other shunt lesions or cardiac defects

- Assessment of rims and adequacy[22]
- Diagnosing associated PAPVC /TAPVC by high index of suspicion and expertise skill.
- Screening for feasibility of intervention
- Rough estimate of flow ratios Qp/Qs
- Could give a clue to search for associated syndromes.
- Monitoring of the procedure
- Follow-up echocardiography[12,13]

RIGHT HEART DIMENSION:

RV DIMENSION:

RV dimension is best evaluated in end-diastole in a specifically focused apical four chamber view of the right ventricle. Utmost precautions are undertaken to prevent foreshortening of the images which is accomplished by viewing the crux of the heart and apex in the same image. Diameter of more than 42 millimeter at the basal level and more than 35 mm at mid cavity level indicates RV enlargement. Likewise, longitudinal or vertical dimension more than 86 millimeters quantifies for RV dilatation / enlargement.

RA DIMENSION:

The apical four chamber view is helpful for evaluation of allows estimation of the RA measurements. Right atrial area greater than

18 cm^2, Right atrial major dimension more than 53 mm, and RA minor dimension more than 44 mm measured at end-diastole quantifies for RA enlargement.

RVOT (RV OUTFLOW TRACT MEASUREMENT):

The proximal diameter measured in the proximal part of RVOT more than 27mm in end-diastole PLAX imaging and the distal diameter at the level of pulmonary valve insertion more than 33mm is diagnostic of RVOT dilatation.

RV SYSTOLIC FUNCTION:

Systolic function of RV[34,36] is assessed by various parameters, such as TAPSE (tricuspid annular plane systolic excursion, normal >15mm), MPI (myocardial performance index by Pulsed Doppler normal values <0.40 and by Tissue Doppler normal values < 0.55, RV FAC (Fractional area change, normal >35 %), Ejection fraction using both two and three dimensional echo and finally, tricuspid lateral annulus peak systolic velocity by tissue-doppler, strain rate and longitudinal strain.[16] Among these, parameters many of the studies have, clearly proven the benefit and clinical utility and importance of MPI, and TAPSE.[11] Hence we analyzed the right ventricular systolic function

using TAPSE, MPI, and isovolumetric acceleration prior to device closure and post device closure immediately, and at one week, and three months.

We also evaluated right atrial dimensions using major and minor dimensions ,and right ventricular dimensions using basal, mid and longitudinal diameters of right ventricle pre and post device closure at follow up of 3 months and compared them with surgical closure.

TREATMENT:

Medical management is usually not necessary preoperatively unless congestive symptoms develop which are managed by diuretic therapy. Arrhythmias may need medical attention for rate control as well as anticoagulant therapy. The main modality of treatment is closure of the defect either by Transcatheter technique or by surgery.

INDICATIONS FOR CLOSURE OF ASD:

Class I Recommendations:-

- Closure either surgically or percutaneously is indicated in the presence of Right ventricular and right atrial enlargement with or maybe without symptoms. (*Evidence: B*)

- Sinus venosus type, primum ASD, or coronary sinus type, must be repaired surgically only. (*Evidence: B*)

Very small septal defects < 5 mm and with nil evidence of right heart volume overload have no influence in the natural history, and prognosis and may not demand closure unless complicated by paradoxical embolism.

Larger defects with right heart volume overload require early closure to prevent complications like:

Decreased exercise tolerance [3,23,24]

Atrial arrhythmias

Embolic complications in pregnancy, Paradoxical embolism [6]

Tricuspid regurgitation

Intractable cardiac failure [7]

Right →Left shunt

Most of the secundum defects could be successfully closed [5] through percutaneous transcatheter method. When this method is not

amenable because of deficiency or inadequacy of rims, or too large for device closure, surgery is recommended.

A multi fenestrated septum or a secundum defect with a large septal aneurysm[26] requires meticulous evaluation by experts in the field of interventional cardiology before device closure is undertaken as the modality of repair. In our study two patients one with a large septal aneurysm and the other with multiple defects in the septum have undergone successful device closure.

CRITERIA FOR IDEAL ASD DEVICE CLOSURE:

- Within the middle of fossa ovalis
- Native size x 1.5 + 14 mm < septal length (LA)
- Sufficient rims:

– Antero Inferior → Mitral rim

– Antero Superior. → Aortic valve rim

– Postero Inferior → IVC rim

– Postero Superior → Right pulmonary venous rims

– Posterior venous rim →SVC rim

In many of the institutes in the world, the preferred option for secundum defects is device closure [45,46]. Trans-catheter closure reduces the hospital stay significantly and offers a speedy recovery, avoidance of surgical scars and their distressing complications[29,30,31,32,33], cosmetic benefit, and provides the same or equivalent hemodynamic benefits as that of surgery.[7,8,35]

INDICATIONS FOR SURGICAL CLOSURE:

Secundum defects > 36 mm

Primum defects

Sino venosus defect

Deficient septal rims

Close proximity and risk of impingement on AV valves, SVC, IVC, Pulmonary veins and coronary sinus

COMPLICATIONS THAT CAN BE ENCOUNTERED IN DEVICE CLOSURE:

Device embolization usually within 20 minutes of procedure [48]

Cardiac perforation

Residual shunts

Erosion of the aortic root

Impingement on systemic and pulmonary vein

Malfunction of the AV valve causing mitral regurgitation

Pericardial effusion/tamponade

Perforation of wall of atrium

Arrhythmias

Sizing balloon rupture

Complications of vascular access

RA –Structures getting entrapped

Defect/Device mismatch

Heart blocks due to encroachment on conduction system

Aortic Regurgitation

INDICATIONS FOR SURGICAL CLOSURE:

Secundum Defects > 36 mm[49]

Primum defects

Sino venosus defect

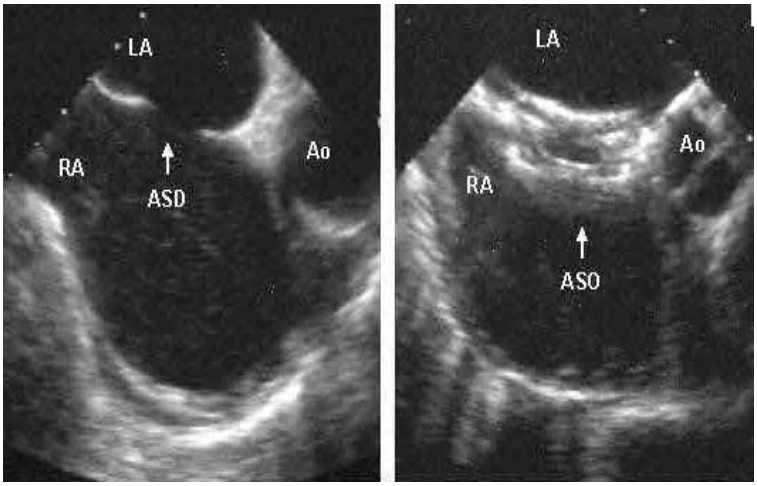
Deficient septal rims

Close proximity with risk of impingement on AV valves, SVC, IVC, Pulmonary veins and coronary sinus

Successful device closure is usually achieved in more than 95% of individuals, [34,50] Trans catheter device closure of secundum defects has an early, faster, and favourable and effect on cardiac remodeling[51,52,53,54].

Individuals following device closure need a thorough clinical assessment, echocardiographic screening of pulmonary artery pressures, Right heart function[13], and monitoring complications, prior to discharge and during early follow-up visits. There is no clear–cut consensus regarding as to what constitutes appropriate follow-up of patients after ASD device closure.

We evaluated patients prior to device closure and monitored them during procedure and immediately post procedure and follow- up echo was done at one week and after 3 months. We also compared the results with that of surgical closure.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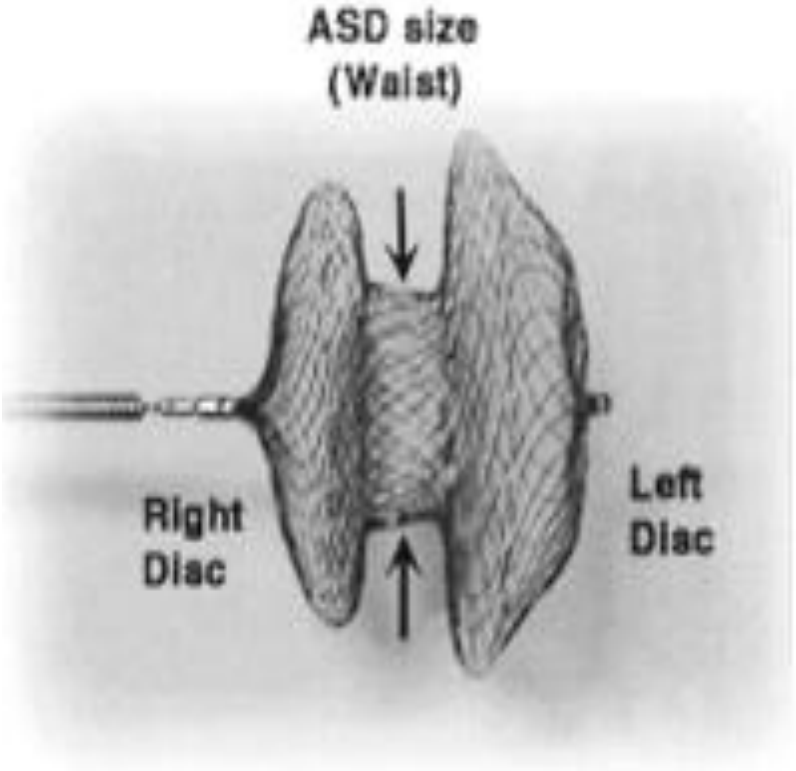

ASD size
(Waist)
Right
Disc
Left
Disc

MATERIALS AND METHODS

All patients with ostium secundum ASD referred for closure were analyzed. Both male and female patients are selected for the study. Relevant history, clinical examination, Pulse oximetry, Xray chest, and E.C.G were taken for all the patients.

All the patients underwent detailed transthoracic and transesophageal echocardiographic study. Echocardiogram was done using Philips HD7XE Echocardiographic machine. The size, site, and number and associated septal aneurysm were well evaluated. Those suitable for device closure were meticulously assessed for adequacy of rims. Those not suited for device closure due to floppy or inadequacy of rims was referred for surgical closure.

The following echocardiographic parameters were measured. We evaluated right atrial dimensions using major and minor dimensions, and right ventricular dimensions using basal, mid and longitudinal diameters, main pulmonary artery dimension (MPA), right ventricular systolic function using Tricuspid annular plane systolic excursion (TAPSE), Myocardial performance index of right ventricle (MPI), and iso-volumetric acceleration (IVA), Tricuspid regurgitation peak gradient (TRPG), prior to device closure and post device closure immediately, and

at one week, and three months using 2D, M-Mode colour doppler, continuous wave doppler, pulse wave and tissue doppler methods and compared them with age and defect size matched individuals who underwent surgical closure.

STUDY DESIGN: Observational study.

TOTAL NUMBER OF PATIENTS INCLUDED IN THE STUDY-60 [30 - device closures, 30 - surgical closures]

INCLUSION CRITERIA:

1. Ostium secundum ASD >12 mm
2. Normal biventricular function
3. Left→Right shunts

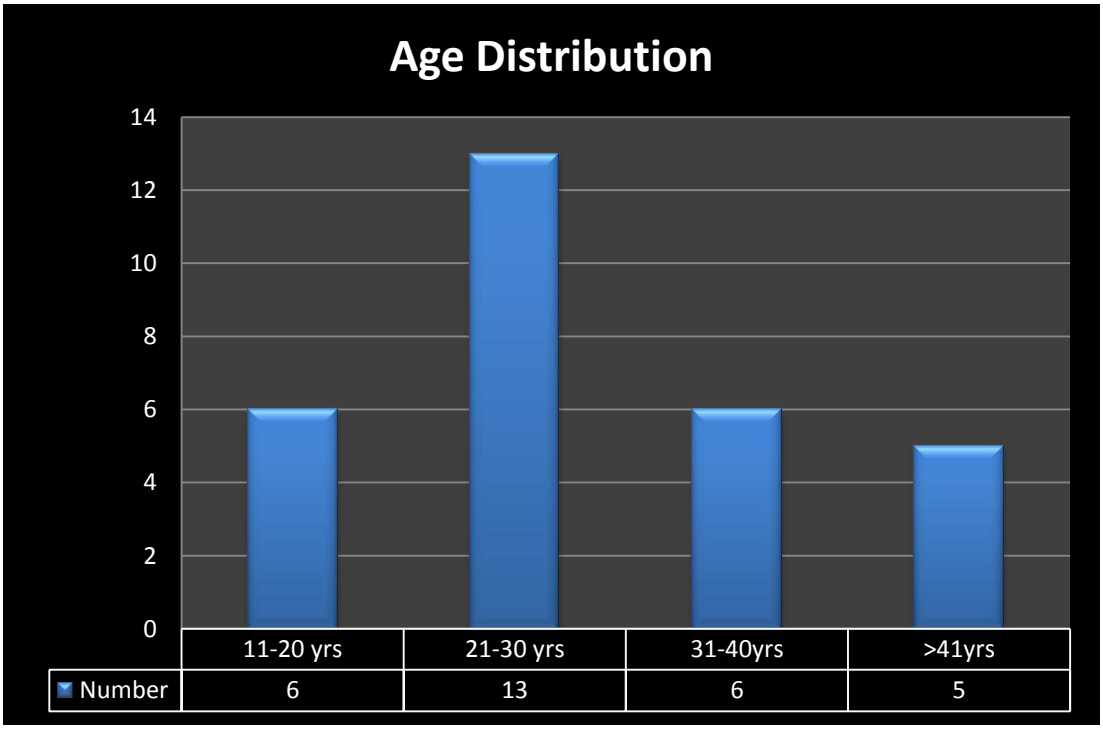
EXCLUSION CRITERIA:

1. Patients with primum or sinus venosus defect.
2. Irreversible pulmonary artery hypertension.
3. Patients with other associated shunts (VSD/PDA) .
4. Patients with a major non-cardiovascular disease .
5. Age less than 12 years
6. Patients with coronary artery disease
7. Unwilling to give consent

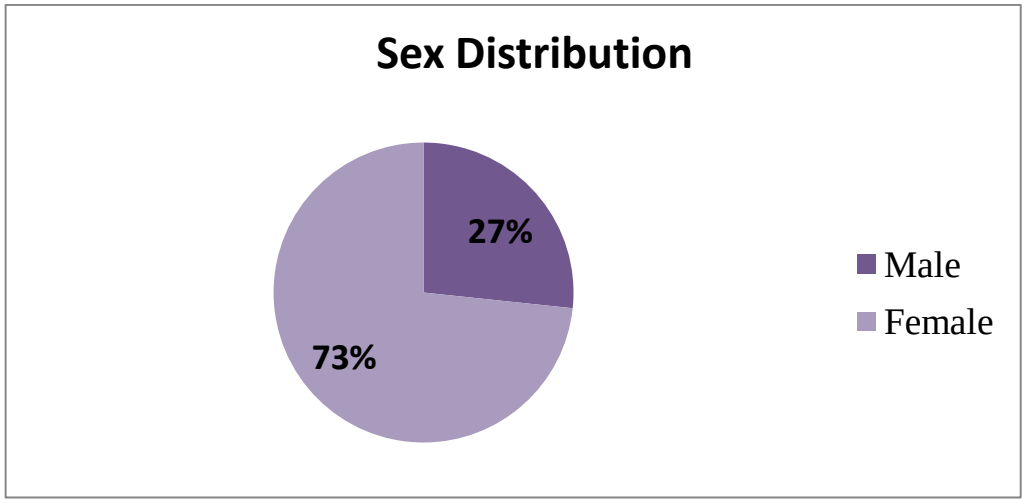
RESULTS AND DATA ANALYSIS

Among the 30 patients optimally selected for ASD device closure by percutaneous transcatheter method after fulfilling the inclusion and exclusion criteria the baseline characteristics are discussed.

AGE distribution for device closure - 15 to 55 years (mean-28.4 years)



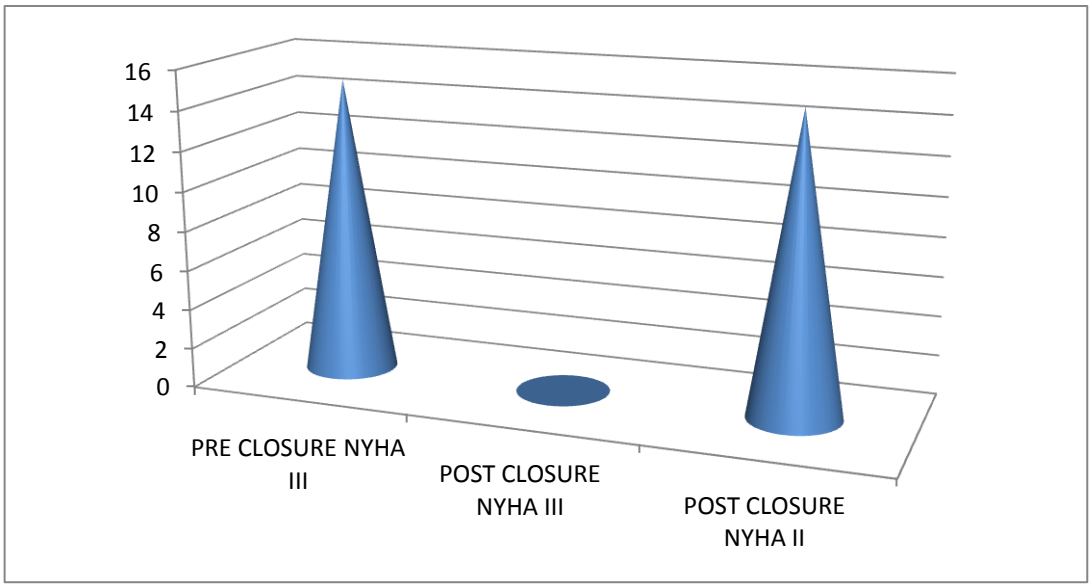
SEX Distribution – Males-8 (27%); Females-22 (73%)



PRE-CLOSURE NYHA FUNCTIONAL CLASS- III (15 patients)

POST DEVICE CLOSURE OUTCOME

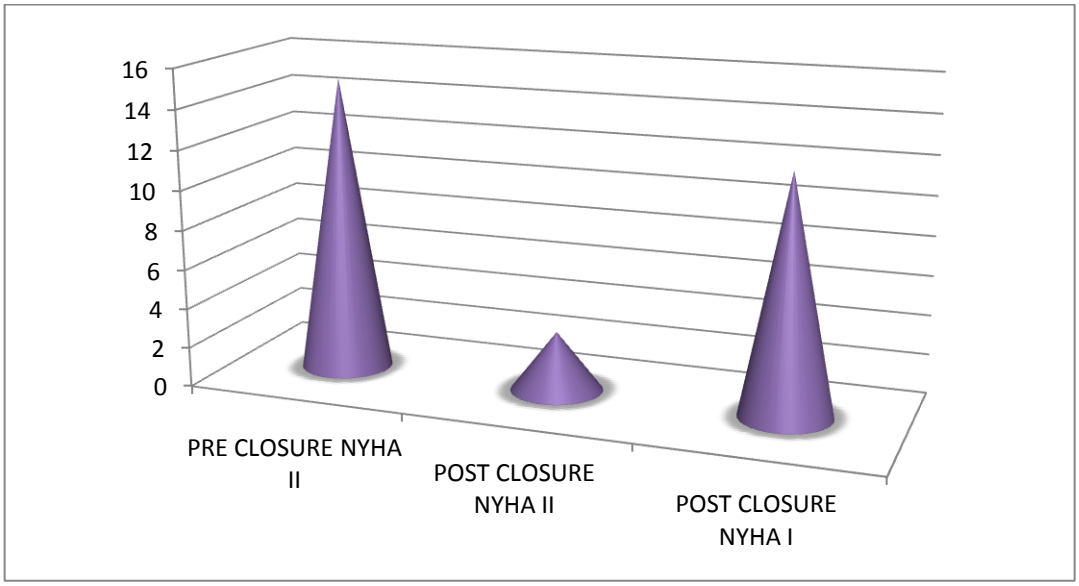
CLASS III→II (15 patients)



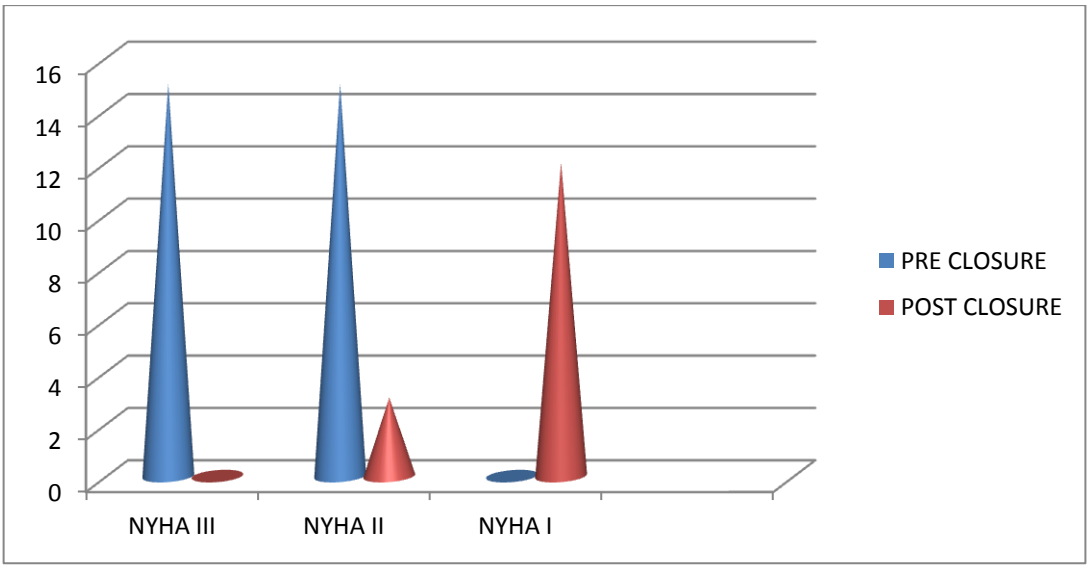
PRE-CLOSURE NYHA FUNCTIONAL CLASS – II (15 patients)

POST DEVICE CLOSURE OUTCOME

CLASS II→I (12 patients)



FINAL OUT-COME OF NYHA FUNCTIONAL CLASS



The mean defect size was 17.06±1.855 SD. The mean device size was 21±1.80 SD

Repeated measure ANOVA is applied to compare the pre closure, post closure, immediate, 1 week and 3 months of the right heart dimension and function parameters

The RV BASAL Diameter pre and post device closure values are tabulated:

	N	**Minimum (cms)**	**Maximum (cms)**	**Mean**	**Std. Deviation**
RVB-preclosure	30	3.9	4.6	4.297	.1847
RVB-postclosure immediate	30	2.7	3.8	3.167	.2202
RVB-postclosure 1 week	30	2.7	3.7	3.167	.2233
RVB-postclosure 3months	30	.0	3.6	2.893	.5813

There is significant difference between 4 time occasions, F=164.228, **P<0.001.** Further multiple comparison of occasions shows all pairs are significantly different at 0.05 level.

The RV mid cavity diameter pre and post device closure is tabulated:

	N	**Minimum (cms)**	**Maximum (cms)**	**Mean**	**Std. Deviation**
RVMid preclosure	30	2.8	4.0	3.610	0.2551
RVMid post closure immediate	30	1.6	3.8	3.027	0.3562
RVMid postclosure 1 week	30	1.7	3.7	2.877	0.3411
RVMid postclosure 3months	30	1.5	3.5	2.710	0.3458

There is significant difference between 4 time occasions, F=359.324**, P<0.001**.

Further multiple comparison of occasions shows all pairs are significantly different.

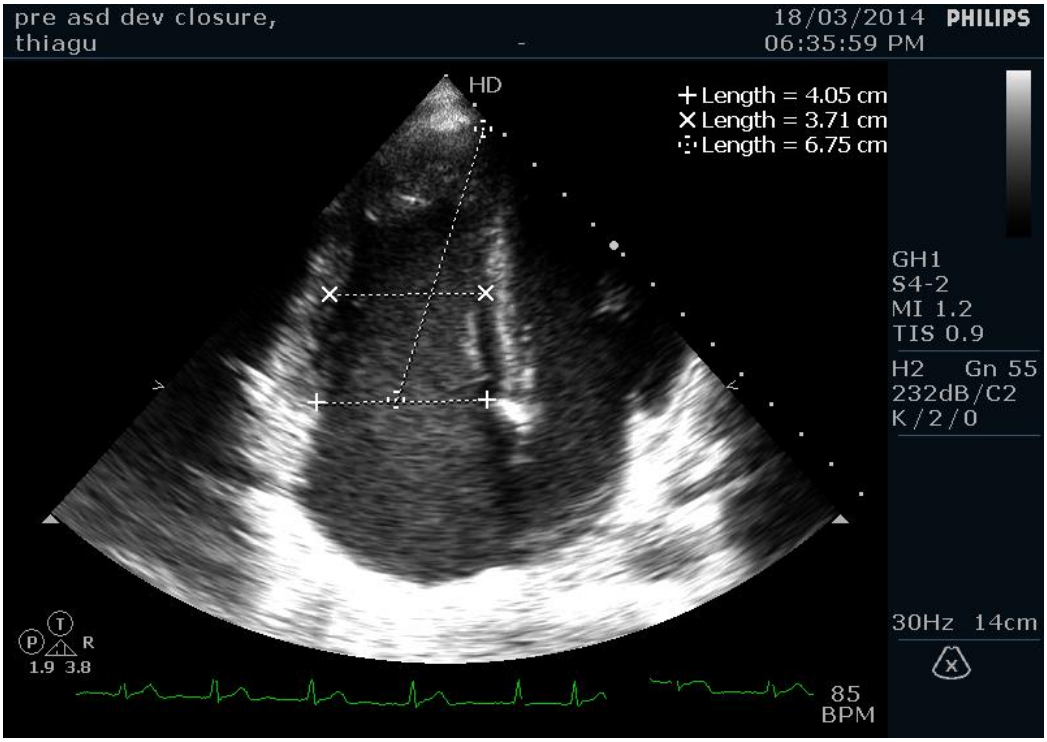
RV Longitudinal dimensions measured pre and post device closure:

	N	Minimum (cms)	Maximum (cms)	Mean	Std. Deviation
RVL preclosure	30	8.0	8.9	8.647	0.2374
RVL postclosure immediate	30	5.2	7.0	6.310	0.4536
RVL postclosure 1week	30	4.9	6.8	6.070	0.4757
RVL postclosure 3months	30	4.8	6.9	5.963	0.4867

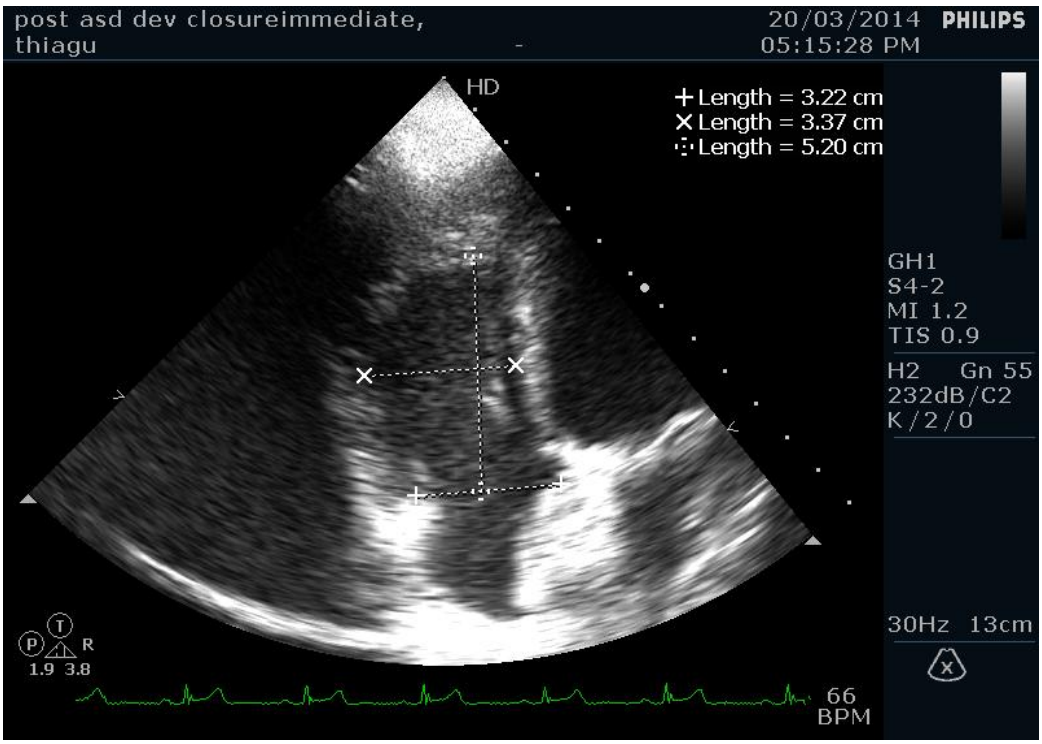
There is significant difference between 4 time occasions, $F=509.617$, $P<0.001$.

Further multiple comparison of occasions shows all pairs are significantly different.

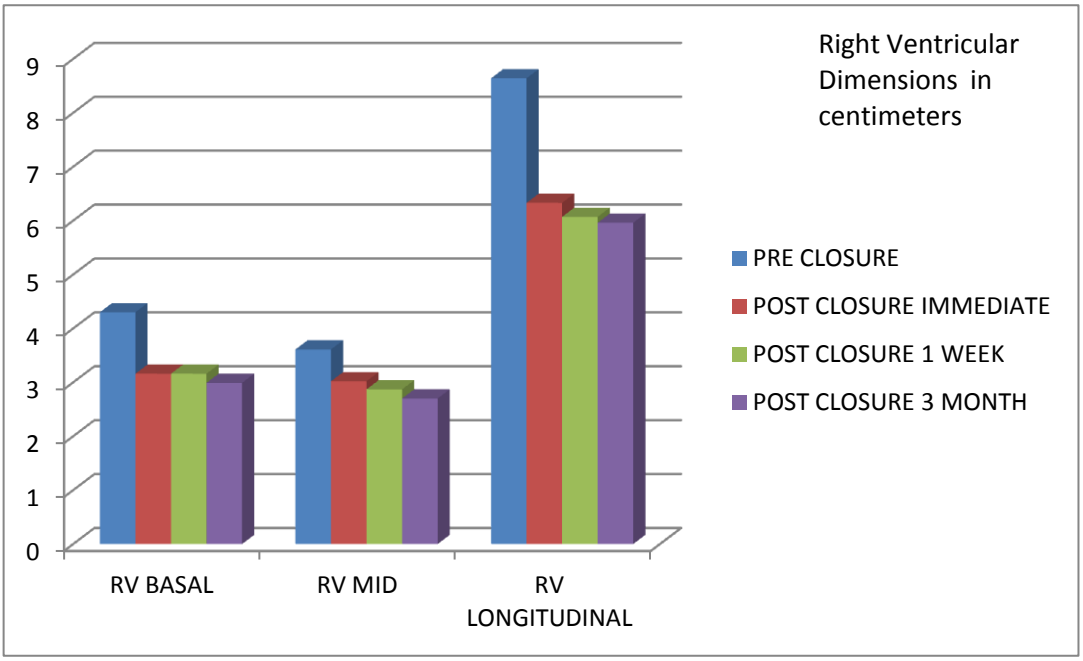
PRE ASD DEVICE CLOSURE RV DIMENSIONS



POST ASD DEVICE CLOSURE IMMEDIATE-IMPACT ON RV DIMENSIONS



COMPARISON OF PRE AND POST CLOSURE RV DIMENSIONS

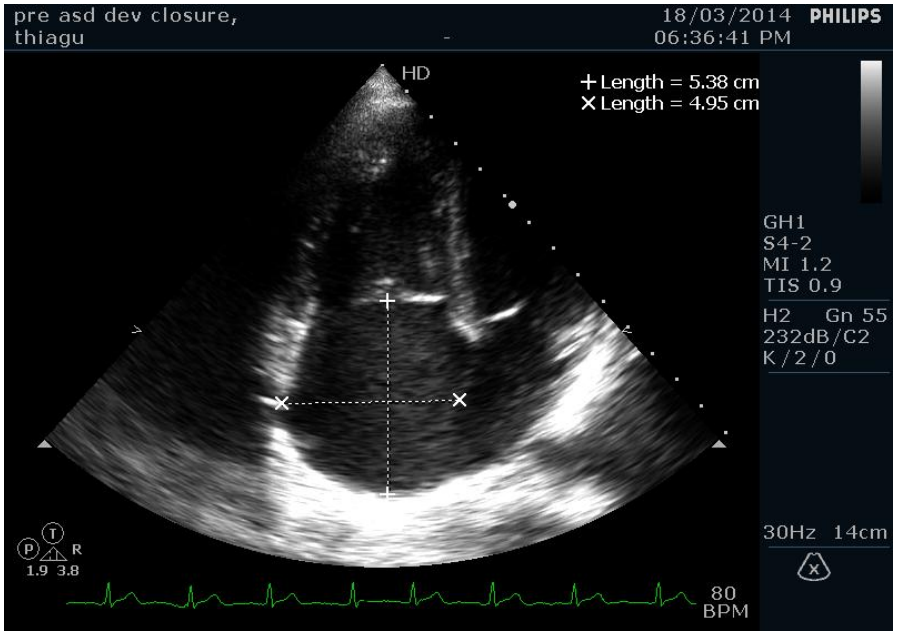


The right atrial major dimensions in (cms) pre and post device closure results:

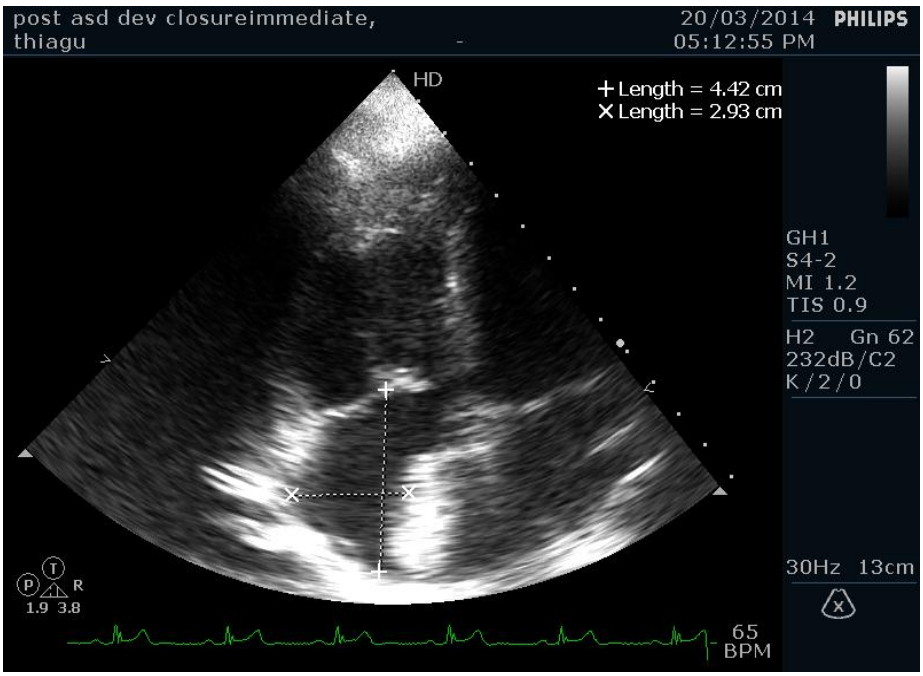
	N	Minimum	Maximum	Mean	Std. Deviation
RA MAJOR preclosure	30	5.1	5.6	5.350	.1408
RA MAJOR-post closure immediate	30	4.1	5.2	4.653	.3501
RA MAJOR post closure 1week	30	4.0	5.1	4.450	.3893
RA MAJOR-post closure 3months	30	3.9	5.0	4.283	.3742

There is significant difference between 4 time occasions, F=180.003, **P<0.001**.

PRE CLOSURE RIGHT ATRIAL MAJOR AND MINOR DIMENSIONS



POST DEVICE CLOSURE IMMEDIATE IMPACT ON RIGHT ATRIAL DIMENSION



RIGHT ATRIAL MINOR DIMENSIONS IN (CMS) PRE AND POST DEVICE CLOSURE RESULTS:

	N	Mini mum	Maxi mum	Mean	Std. Deviation
RA MINOR preclosure	30	3.9	5.0	4.547	0.2933
RA MINOR postclosure immediate	30	2.8	4.9	3.870	0.5266
RA MINOR postclosure 1 week	30	2.7	4.8	3.710	0.5155

There is significant difference between 4 time occasions, F=58.655, **P<0.001**.

FINAL OUTCOME OF RIGHT ATRIAL DIMENSIONS PRE AND POST ASD DEVICE CLOSURE

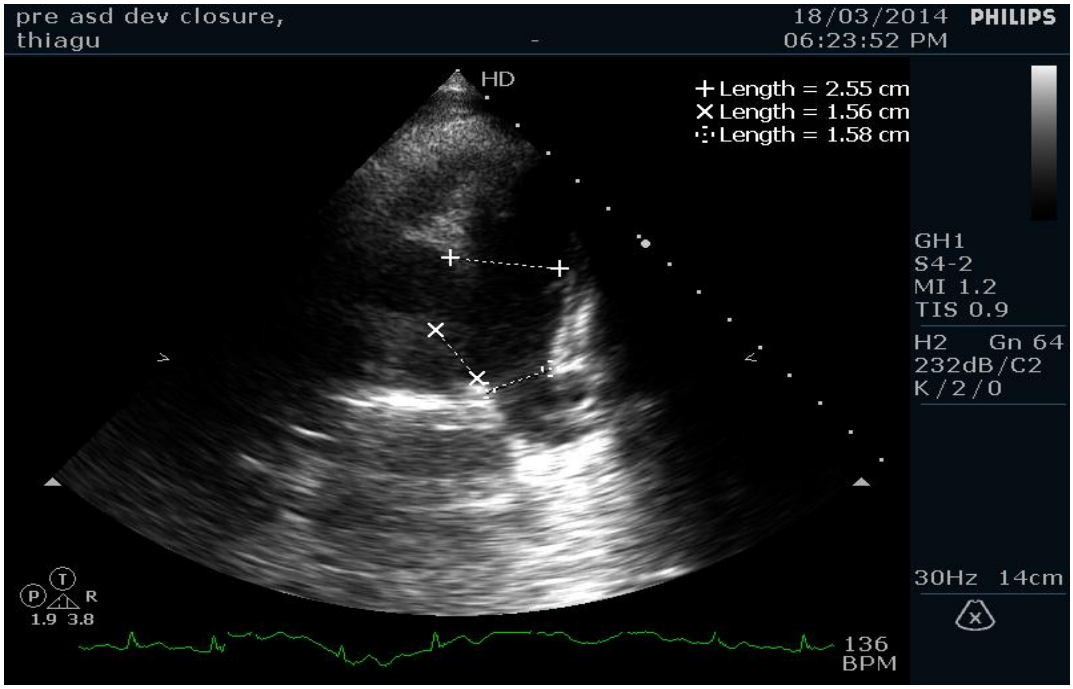
Main pulmonary artery dimensions in (cms) pre and post device closure:

	N	Minimum	Maximum	Mean	Std. Deviation
MPA diameter preclosure	30	2.5	3.5	2.960	0.2094
MPA diameter postclosure immediate	30	2.2	3.1	2.640	0.1958
MPA diameter post closure 1 week	30	2.1	3.0	2.533	0.2073
MPA diameter postclosure 3 months	30	2.0	2.6	2.310	0.1768

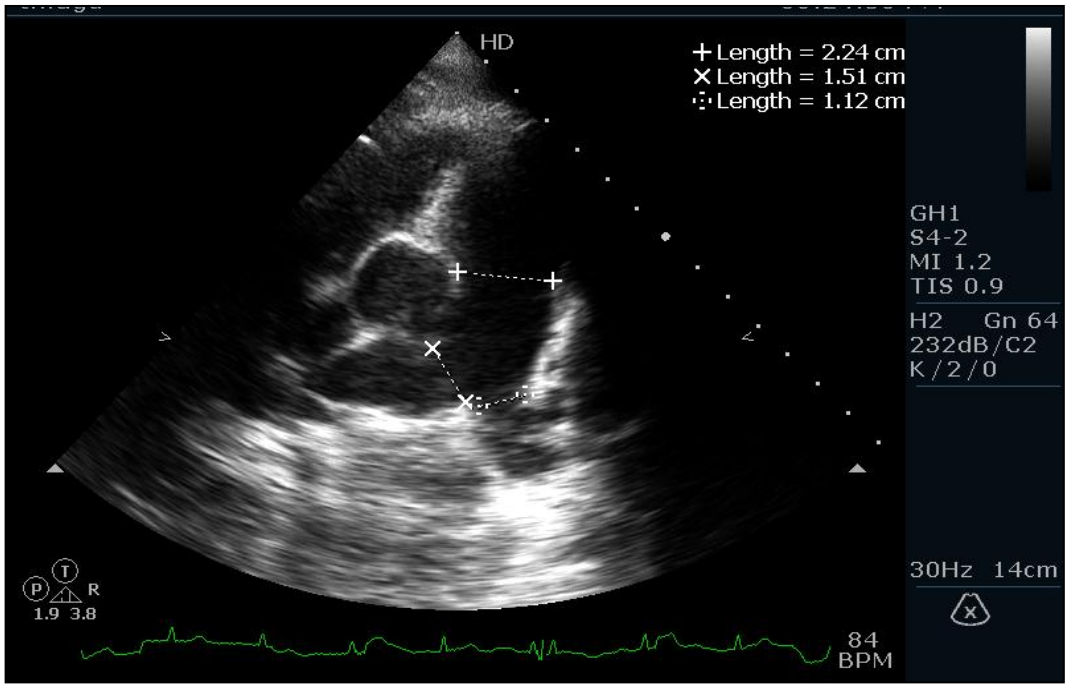
There is significant difference between 4 time occasions, F=444.425, **P<0.001**.

Further multiple comparison of occasions shows all pairs are significantly different

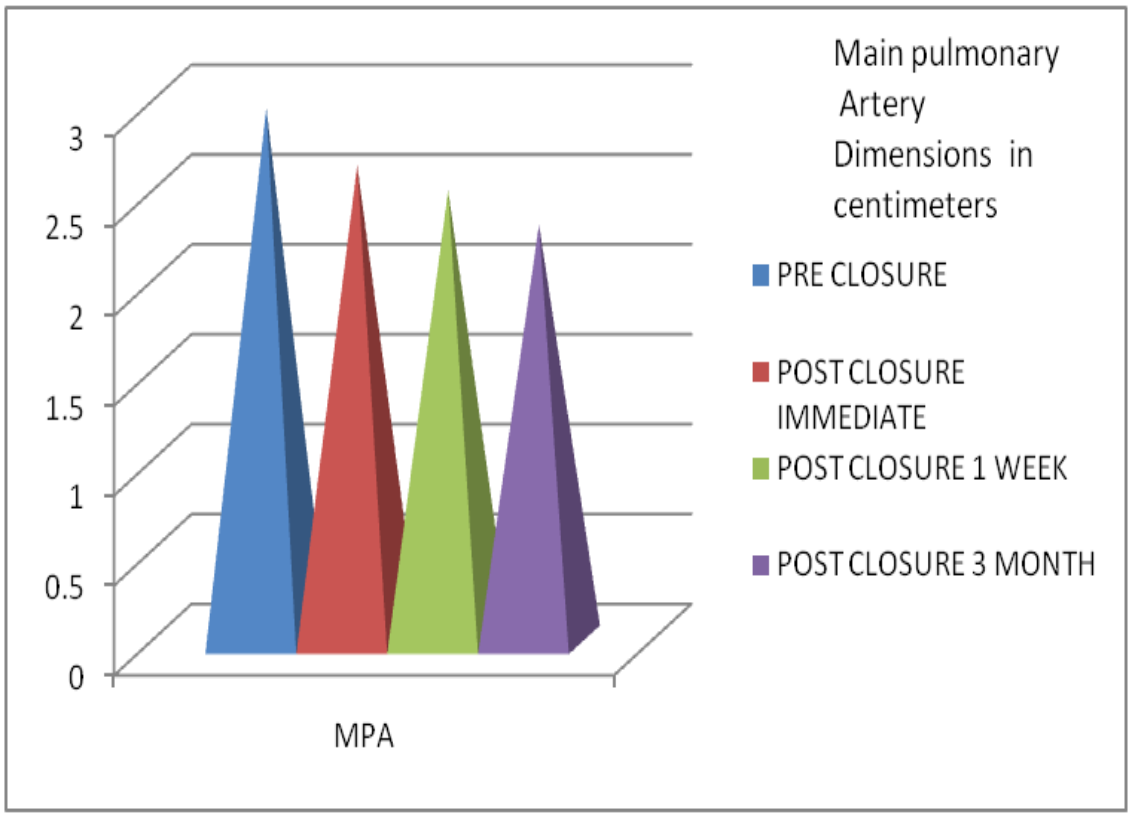
PRE CLOSURE MPA DIMENSIONS



POST ASD DEVICE CLOSURE MPA DIMENSIONS IMMEDIATE



FINAL OUTCOME OF MPA DIMENSIONS PRE AND POST DEVICE CLOSURE:

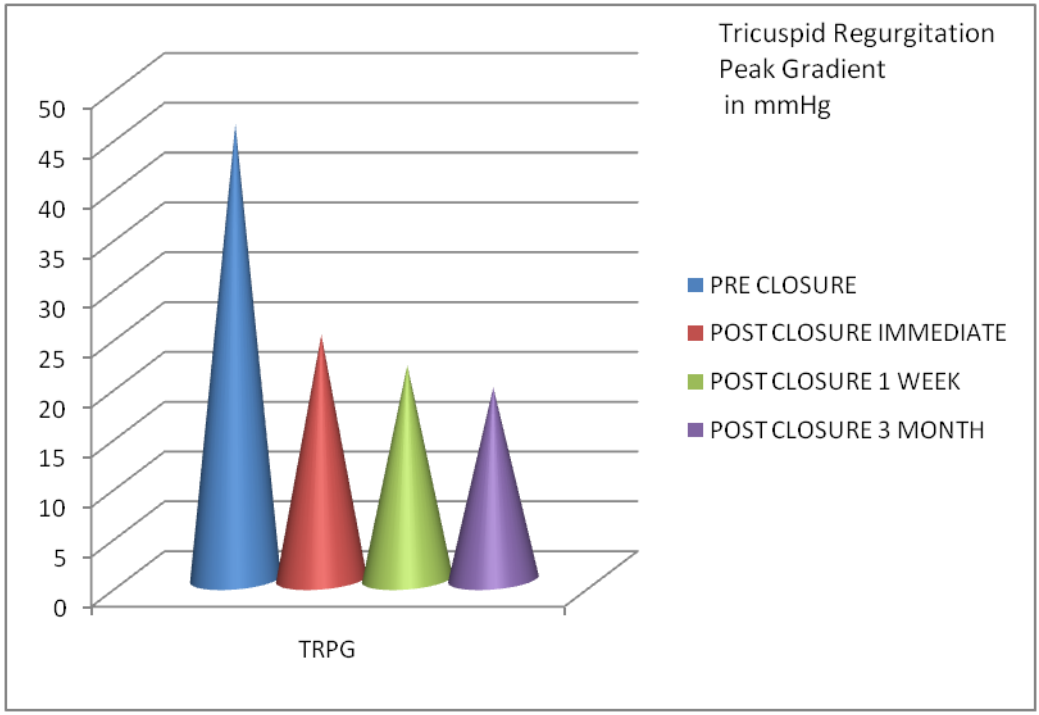


COMPARISON OF TR PEAK GRADIENT PRE AND POST ASD DEVICE CLOSURE:

	N	Minimum mmHg	Maximum mmHg	Mean	Std. Deviation
TRPG preclosure	30	20.0	52.0	45.700	6.3145
TRPG postclosure immediate	30	9.7	32.0	24.523	4.6248
TRPG postclosure 1 week	30	12.0	26.0	21.467	2.6488
TRPG postclosure 3months	30	9.0	24.0	19.233	3.0021

There is significant difference between 4 time occasions, F=509.363, **P<0.001.**

COMPARISON OF TR PEAK GRADIENT PRE AND POST ASD DEVICE CLOSURE

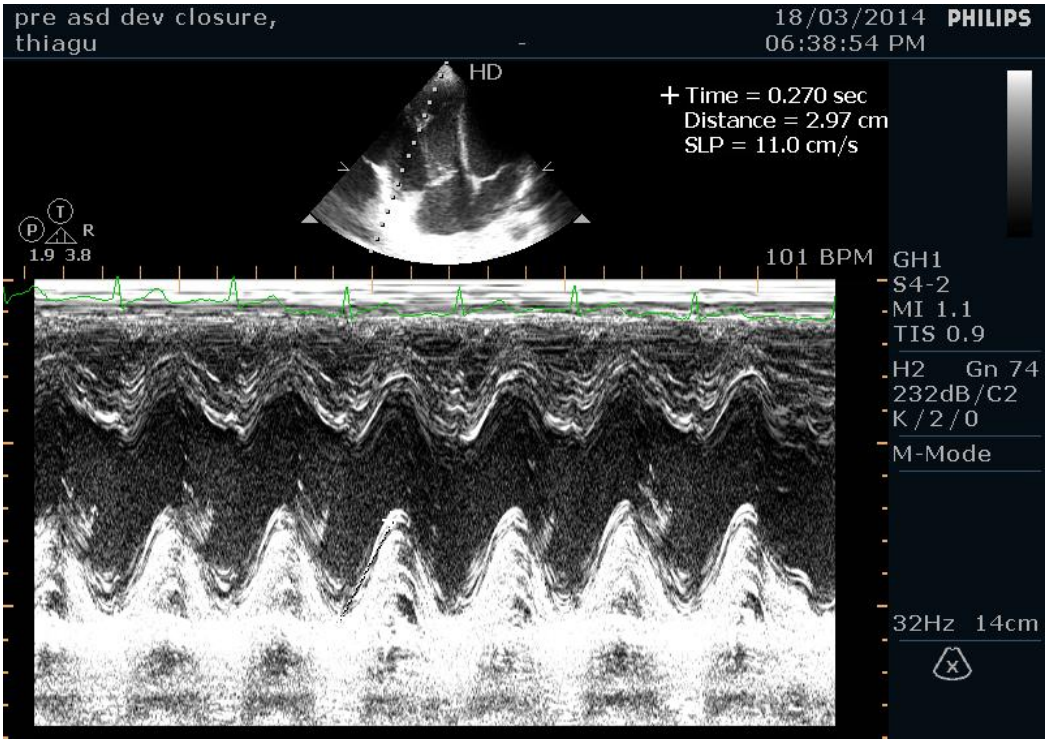


COMPARISON OF TAPSE in mm PRE AND POST DEVICE CLOSURE:

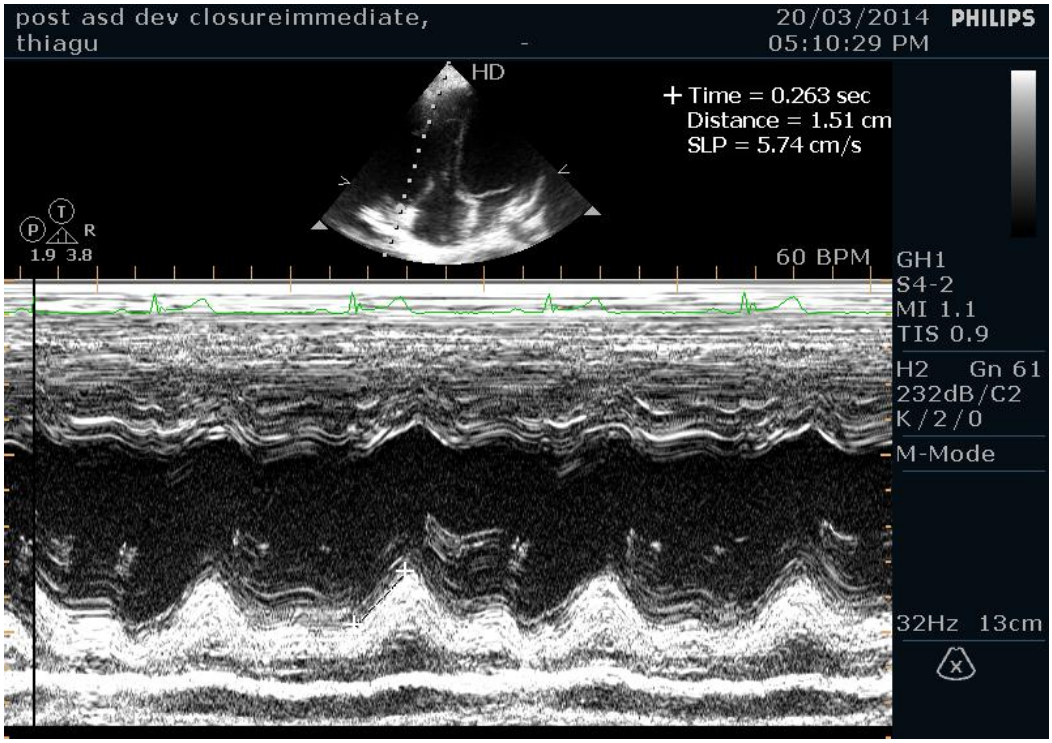
	N	Minimum	Maximum	Mean	Std. Deviation
TAPSE preclosure	30	23.0	29.0	25.367	1.6501
TAPSE postclosure immediate	30	20.0	26.0	22.833	1.5105
TAPSE postclosure 1 week	30	19.0	24.0	21.500	1.4081
TAPSE postclosure 3 months	30	18.0	22.0	19.633	1.2172

There is significant difference between 4 time occasions, F=370.577, **P<0.001.**

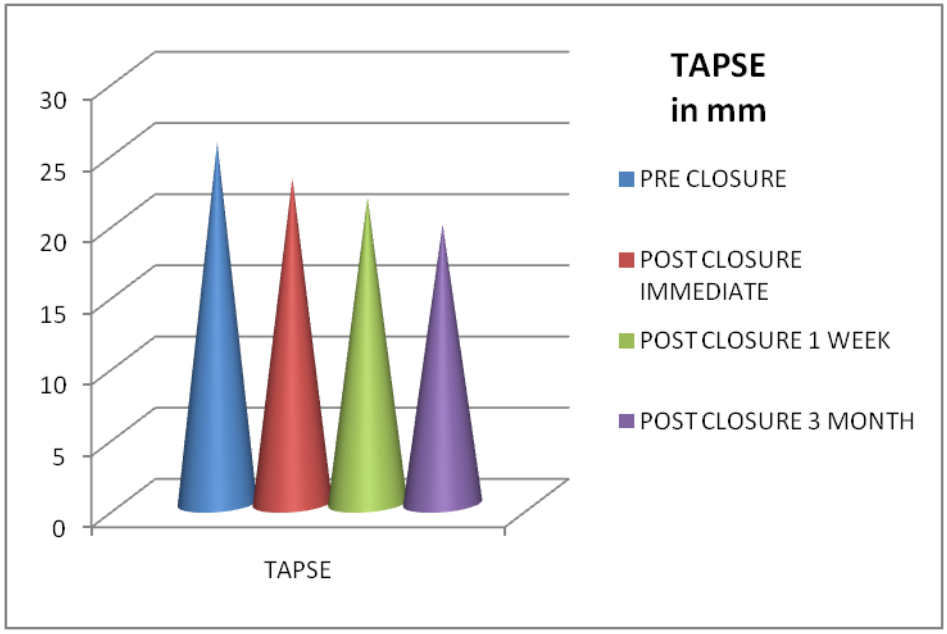
PRE DEVICE CLOSURE TAPSE



POST ASD DEVICE CLOSURE - IMMEDIATE IMPACT ON TAPSE REDUCED FROM 29MM TO 15.1 MM



FINAL OUTCOME OF TAPSE PRE AND POST ASD DEVICE

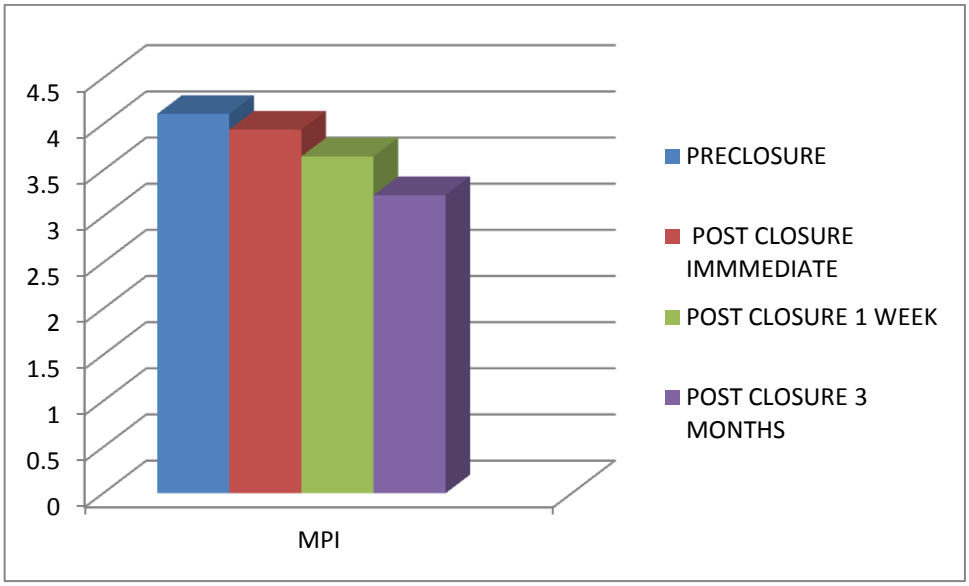


COMPARISON OF MYOCARDIAL PERFORMANCE INDEX (MPI) PRE AND POST ASD DEVICE CLOSURE:

	N	Minimum	Maximum	Mean	Std. Deviation
MPI preclosure	30	3.2	4.9	4.113	.4345
MPI post closure immediate	30	3.2	4.9	3.943	.4141
MPI post closure 1 week	30	3.0	4.8	3.653	.5015
MPI post closure 3 months	30	2.7	4.7	3.233	.4823

There is significant difference between 4 time occasions, F=45.367, **P<0.001**

FINAL OUTCOME OF MPI PRE AND POST ASD DEVICE CLOSURE



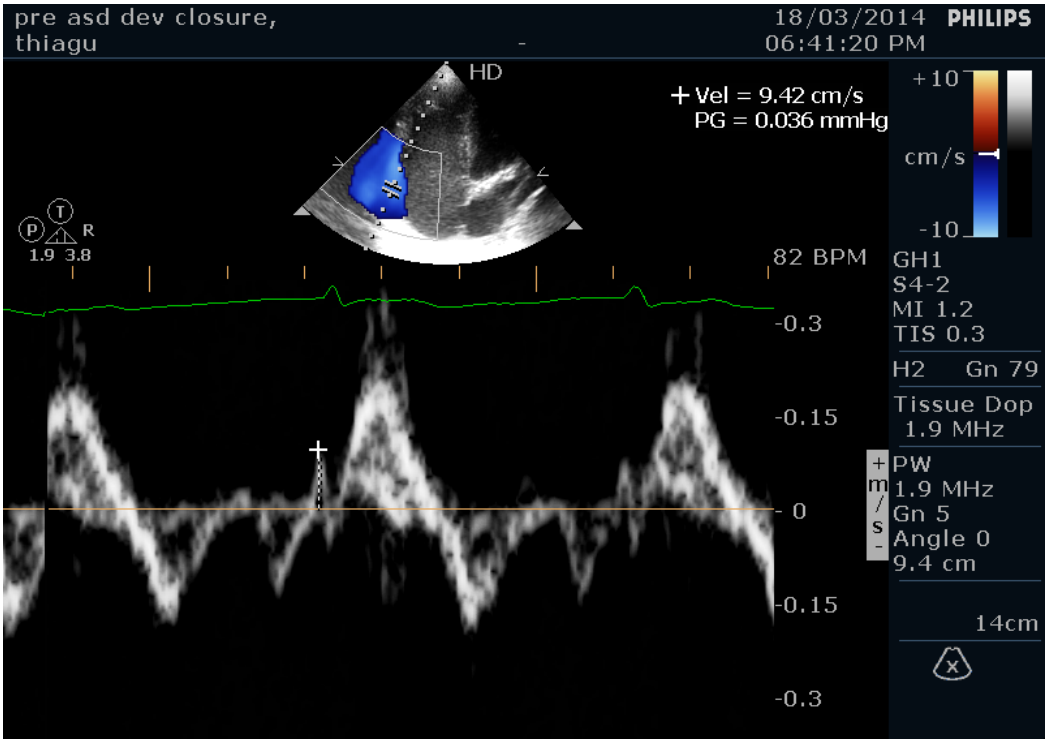
COMPARATIVE DATA ON ISOVOLUMIC ACCELERATION (ISA) PRE AND POST ASD DEVICE CLOSURE:

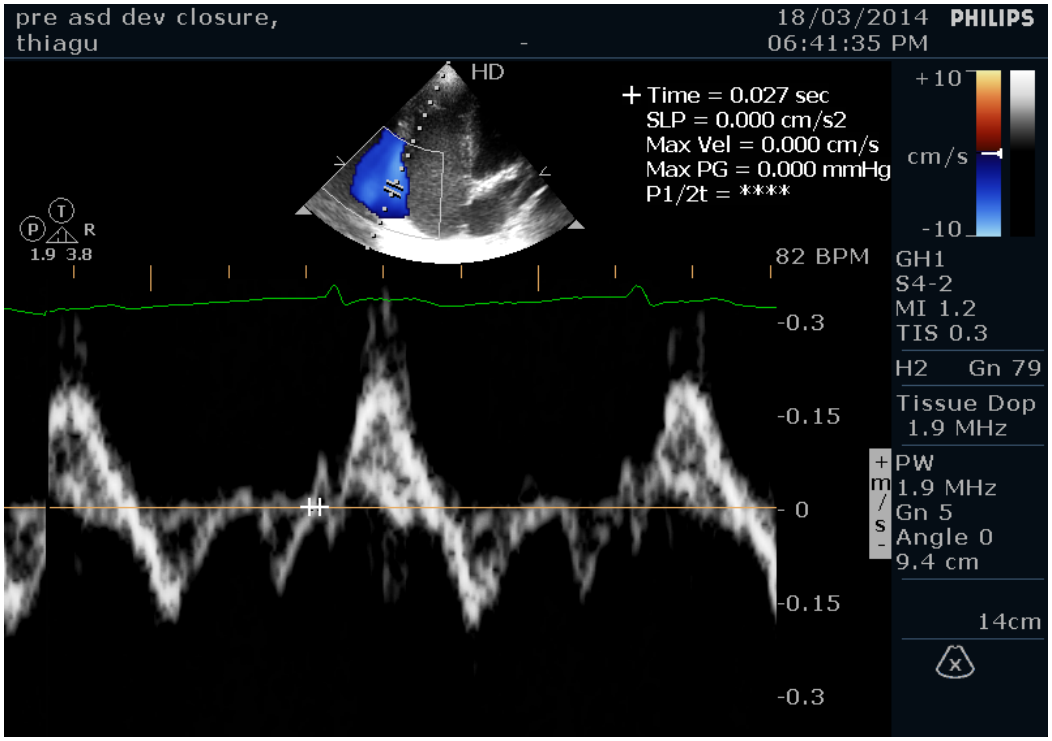
	N	Mini mum	Maxi mum	Mean	Std. Deviation
ISA pre closure	30	2.5	3.5	2.960	.2253
ISA post closure immediate	30	2.2	3.1	2.643	.2029
ISA post closure 1 week	30	2.1	3.0	2.547	.2330
ISA post closure 3 months	30	2.1	2.8	2.347	.1925

There is significant difference between 4 time occasions, F=228.286, **P<0.001.**

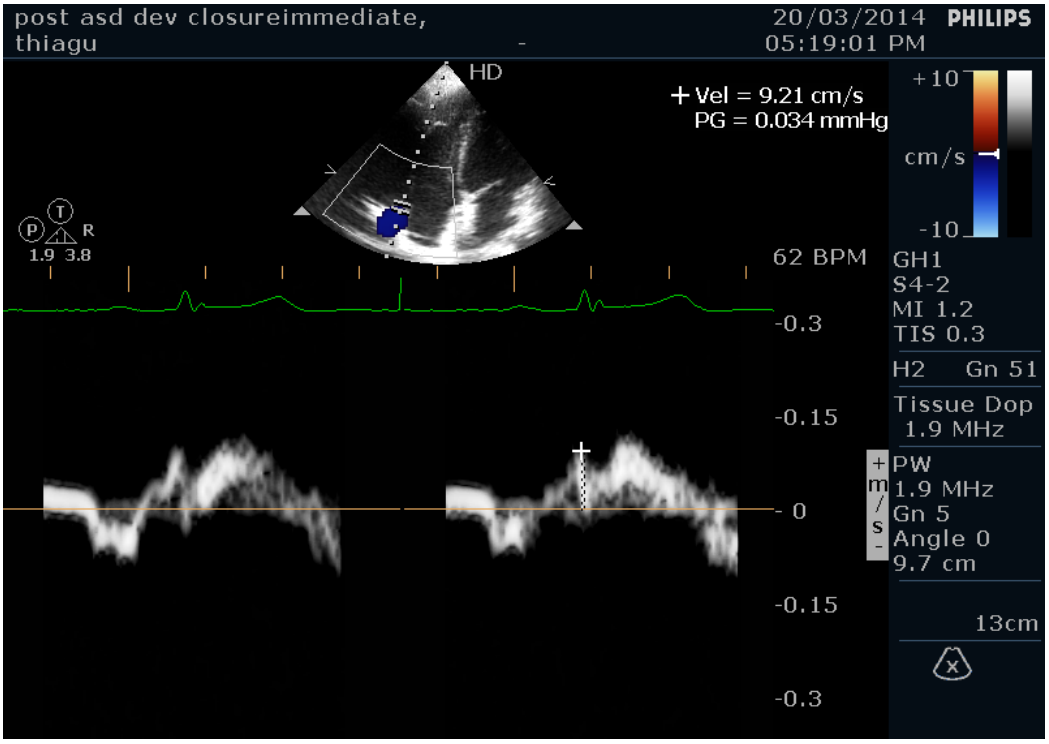
Further multiple comparison of occasions shows all pairs are significantly different.

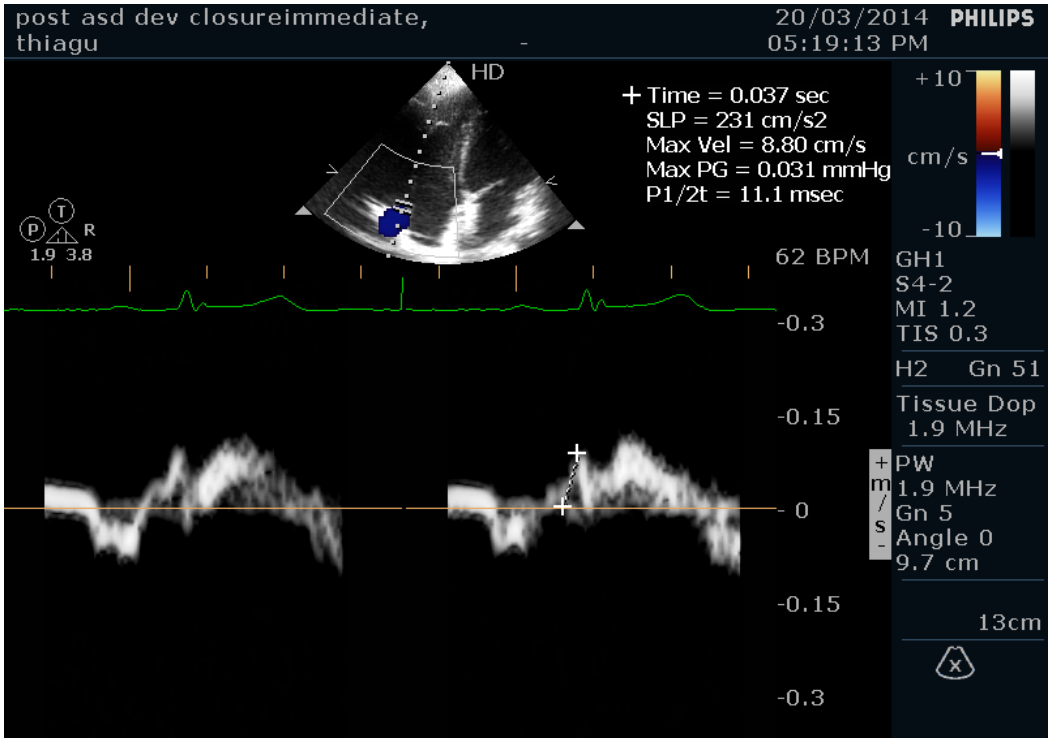
ISOVOLUMIC ACCELERATION IS MEASURED BY FINDING THE QUOTIENT OF ISOVOLUMETRIC ACCELERATION VELOCITY DIVIDED BY TIME





ISOVOLUMIC ACCELERATION POST ASD DEVICE CLOSURE IMMEDIATE





Surgical closure patients mean and standard deviation of age distribution and defect size:

	N	Minimum	Maximum	Mean	Std. Deviation
AGE	30	14.0	59.0	28.467	9.4485
DEFECT SIZE	30	17.0	26.0	20.633	1.9384

Comparison of age between device closure and surgical closure group Student t test is used.

Group Statistics						
	Group	**N**	**Mean**	**Std. Deviation**	**t value**	**P value**
Age	Device closure	30	28.400	9.4490	0.014	P>0.05 NS
	Surgical closure	30	28.367	9.4485		

Comparison of Device closure and surgical closure group

Student t test is used to compare mean scores

Group Statistics							
	GROUP	**N**	**Mean**	**Std. Deviation**	**t value**	**DF**	**P value significance**
RV Basal dm	PreDevice closure	30	4.297	.1847	-2.582	58	P=0.012*
	PreSurgical closure	30	4.440	.2415			
RV Basal dm 3 month	PostDevice closure	30	2.893	.5813	.693	58	P=0.491 NS
	PostSurgical closure	30	2.817	.1724			
RV Mid	PreDevice closure	30	3.610	.2551	-1.045	58	P=0.300 NS
	PreSurgical closure	30	3.677	.2388			
RV Mid 3 month	PostDevice closure	30	2.710	.3458	3.155	58	P=0.003*
	PostSurgical closure	30	2.467	.2426			
RVL	PreDevice closure	30	8.647	.2374	-2.978	58	P=0.004*
	PreSurgical closure	30	8.900	.4009			
RVL 3 month	PostDevice closure	30	5.963	.4867	2.012	58	P=0.049*
	PostSurgical closure	30	5.750	.3170			
RA Major dm	PreDevice closure	30	5.350	.1408	4.662	58	P<0.001*
	PreSurgical closure	30	5.060	.3103			
RA Major dm 3 month	PostDevice closure	30	4.283	.3742	1.981	58	P=0.052 NS
	PostSurgical closure	30	4.090	.3818			

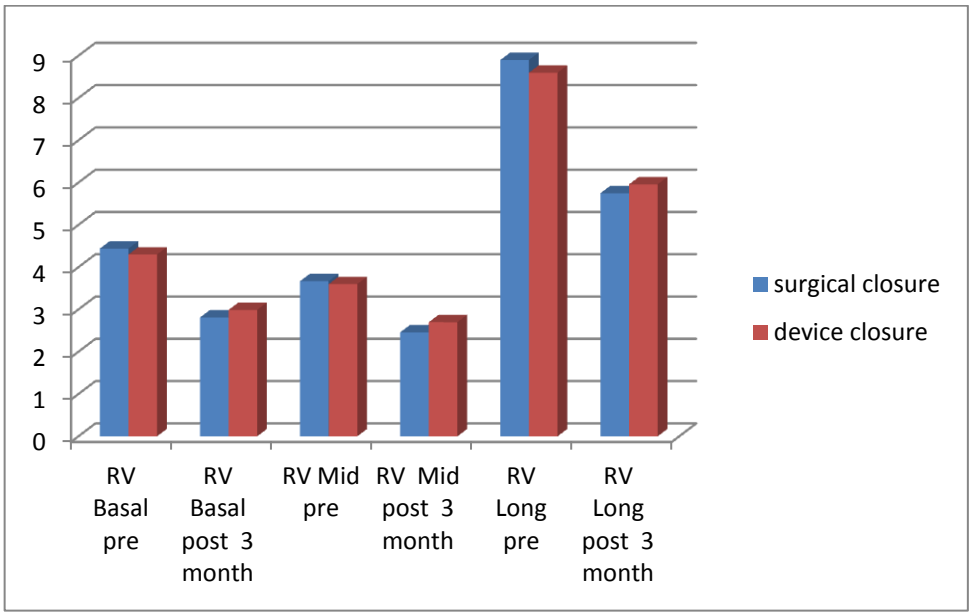
Group Statistics							
	GROUP	**N**	**Mean**	**Std. Deviation**	**t value**	**DF**	**P value significance**
RA Minor dm	PreDevice closure	30	4.547	.2933	1.617	58	P=0.111 NS
	PreSurgical closure	30	4.427	.2815			
RA minor dm 3 month	PostDevice closure	30	3.563	.5096	.220	58	P=0.827 NS
	PostSurgical closure	30	3.537	.4263			
TRPG	PreDevice closure	30	45.700	6.3145	-1.361	58	P=0.179 NS
	PreSurgical closure	30	47.500	3.5501			
TRPG 3 month	PostDevice closure	30	19.233	3.0021	-1.429	58	P=0.158 NS
	PostSurgical closure	30	20.200	2.1719			
MPI	PreDevice closure	30	4.113	.4345	.464	58	P=0.644 NS
	PreSurgical closure	30	4.067	.3387			
MPI 3 month	PostDevice closure	30	3.233	.4823	-1.784	58	P=.080 NS
	PostSurgical closure	30	3.447	.4431			

NS NOT SIGNIFICANT

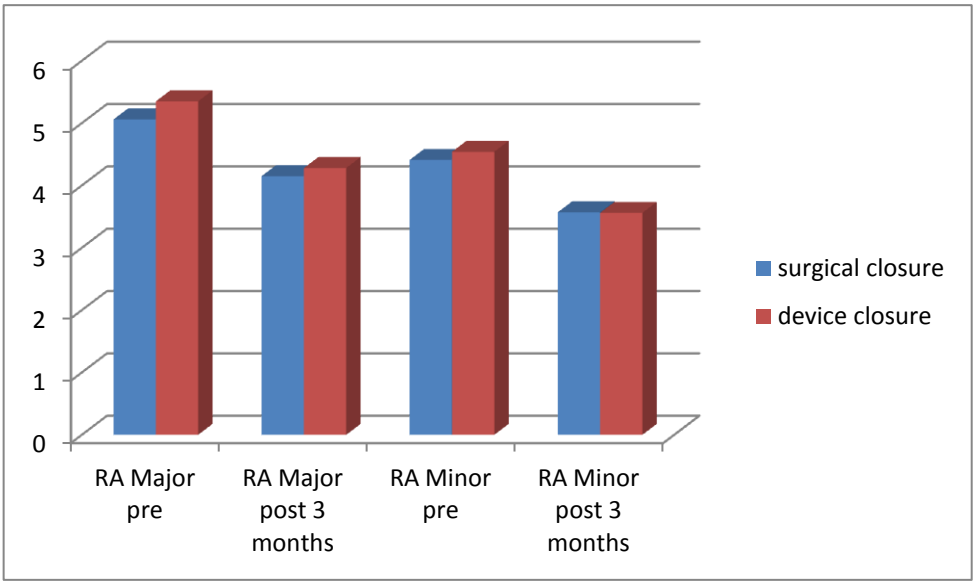
* SIGNIFICANT

FINAL COMPARISON OF OUTCOME BETWEEN DEVICE CLOSURE PATIENTS AND SURGICAL GROUP - PRE AND POST 3 MONTH ANALYSIS

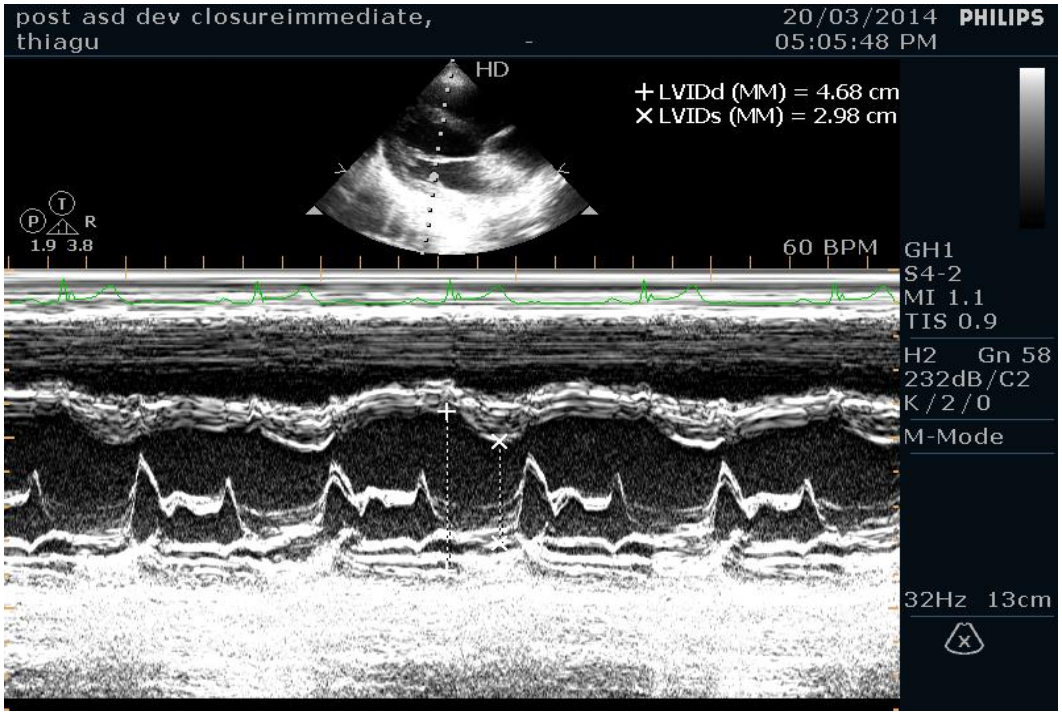
RV DIMENSIONS: COMPARISON OF SURGICAL AND DEVICE CLOSURE OUTCOMES



RIGHT ATRIAL DIMENSIONS: COMPARISON OF SURGICAL AND DEVICE CLOSURE OUTCOMES

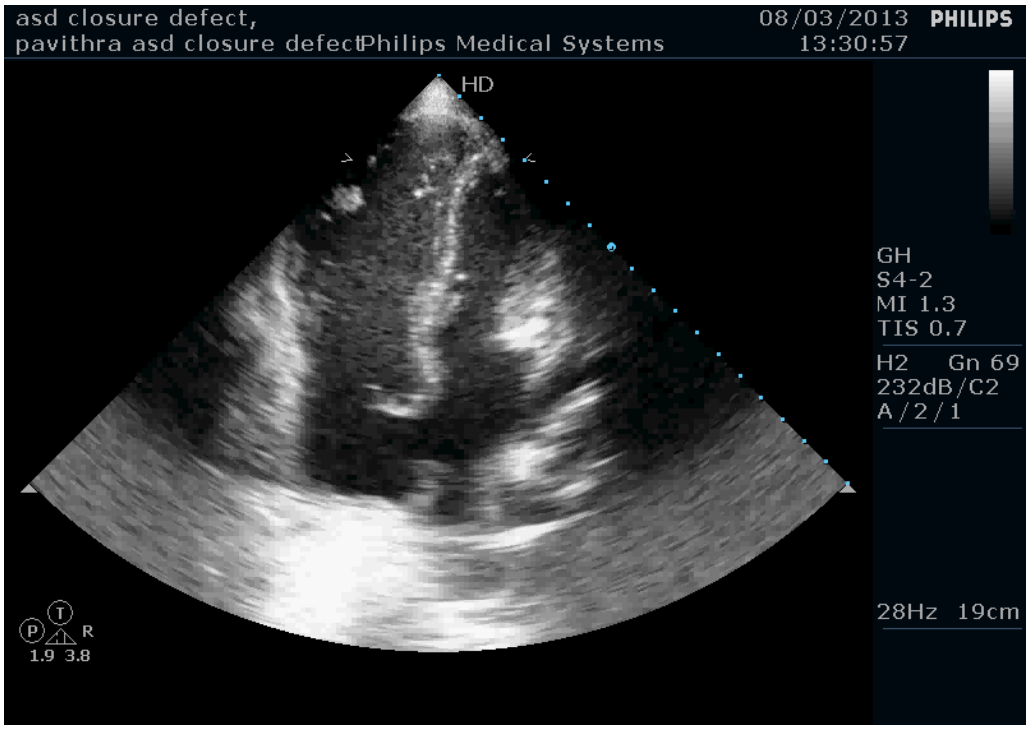


NO EVIDENCE OF PARADOXICAL SEPTAL MOVEMENT IN THE POST DEVICE CLOSURE PERIOD



Among the 30 patients referred for surgical closure was successful in all of them except in one patient who developed pericardial patch dehiscence at 3 months follow up period

PERICARDIAL PATCH DEHISCENCE IN 1 POST SURGICAL PATIENT



DISCUSSION

This study was mainly undertaken to establish the beneficial effects of percutaneous transcatheter device closure in optimally selected patients with ostium septum defects and the impact of device closure on the right heart dimensions and functions.

Among the 32 patients selected for device closure, 12 patients with deficient aortic rims ,one patient with atrial septal aneurysm, and 1 patient with multiple secundum defects, we were successful in deploying the amplatzer septal occluder[5,4],in 4 patients,andcocoon septal occluder in 26 patients. 2 patients were deferred after an attempt due to floppy IVC rims. All the 30 patients who underwent successful device closure were closely observed pre procedurally with transthoracic and transesophageal echo, and during procedure with TEE, and post procedurally immediately, after 1 week, and after 3 months. None of the procedural or post procedural complications like device embolisation, erosion, or heart blocks noted in our patients, except that 4 patients had transient atrial arrhythmias during the procedure which spontaneously reverted in 2 of them, and which necessitated adenosine for reversion to sinus rhythm in 2 patients. Arrhythmias were not encountered in any of them in the post procedure follow up period.

The minimum fluoroscopic time was 8 minutes and the maximum fluoroscopic time was 48 minutes and the mean fluoroscopic time was 28 minutes ±7 minutes. Balloon sizing was done for 3 patients. In 28 patients the device was deployed by parking the multipurpose catheter and 0.035" terumo guide wire in the left upper pulmonary vein and in two patients in the right upper pulmonary vein.

All patients received 100 units/kg of unfractionated heparin during the procedure and preprocedure 300 mg of aspirin which was continued as 150 mg /day following the procedure for 6 months period. No thromboembolic complications were noted in our patients.

All patients were discharged on the third post intervention day. The right atrial major and minor dimensions and right ventricular basal, midcavity and longitudinal dimensions ,main pulmonary artery dimensions, pulmonary hypertension as assessed by TRPG, were noted in the pre procedure period and immediately after the procedure, and 1 week, and at 3 months follow up period. Likewise RV systolic functions were assessed using TAPSE, MPI and isovolumetric acceleration.

Statistical analysis revealed that the mean age for device closure was 28.4(range between 15-55 years.) Females dominated the sex

distribution contributing to 73% and males 23%. The NYHA functional class improved by one functional class in 90% of the individuals. The preprocedural mean RA major and minor dimensions and RV dimensions were significantly reduced by device closure, in the immediate, 1 week and after 3 months of followup. The reduction in right heart dimensions were consistent in the immediate post intervention period, which showed further reduction at 3 months and was statistically significant. Pulmonary hypertension almost normalized in all the patients at 3 months of followup. There was a gradual decline in the TRPG during the follow up period from 45.7±6.37 mmHg to 19.23±3 mmHg which was statistically significant. The MPA dimensions reduced from a mean diameter of 2.96 cm to 2.31 cm which is statistically significant.

Actually TAPSE a marker of RV systolic function though remained normal throughout the study period, reduced from a mean value of 25.36 mm to 19.6 mm which is statistically significant. The reduction in TAPSE could well be explained by the fact that during the preprocedure period when the volume overload to the RV is more the tricuspid annular excursion is more so that it can offload the overloaded right heart, whereas during the post intervention period the closure of the septal defect halts the gushing of blood into the right heart system thus not requiring the excessive tricuspid annular excursion.

MPI though within normal limits throughout the study period significantly improved in the post closure period.

Isovolumic acceleration a load independent determinant of RV systolic function remains stable or improves following device closure. The outcome was better in individuals in whom the defect was closed at an earlier age than those closed at a later age group [Better outcome in age less than 20 years when compared to age > 40 years matched by defect size].This could well explain the chronological impact of volume overload on the right heart and its thrust on the remodeling and hemodynamics of right heart dimension and function. The results of device closure at 3 months follow up when compared to age and defect size, matched surgical closure results in 30 patients and were not statistically significant proving the outcome of transcatheter closure non inferior to surgical closure of ASD.

All patients had normal LV systolic function at follow up of 3 months but all patients in the surgical closure group had abnormal or paradoxical ventricular septal motion. Among the 30 patients who underwent surgical closure successfully only one patient had pericardial patch dehiscence at 3 months follow up

Comparison of our study with other published data:

In one study by salehain et al [14] which proved improvement of RV function and performance after device closure of septum secundum defects.

But in another study by Eidem et al[11] did not report on improvement of right heart function. Giardini et al [42] showed improved LV systolic function due to normalization of paradoxical septal motion after device closure.

Another study by kort et al[28] which demonstrated decrease in RA area and RV dimensions followed up in 24 hrs, 1 month and 3 months period and 2 years followup. A recent study published in Am.JAC, 2012 which compares the outcome of surgical versus device closure in adults closely resembles our study.

Percutaneous device closure outweighs surgical closure in the following
ways:

1. No Scar
2. Lesser hospital stay (3 days)
3. Less Morbidity
4. Avoiding opening of the pericardium as in surgical closure thus preventing abnormal/paradoxical ventricular septal motion.
5. Avoidance of thoracotomy and its complications

Unique features pertinent to our study:

Most of the studies failed to unravel the outcome of right heart hemodynamics, function and dimension in the immediate post device closure period, which is very well evaluated in our study the first of its kind.

Most of the data published so far either took into account the right heart dimensions alone, or right heart functions only, or compared them with surgical closure. Our study is a Comprehensive one which encompasses most of the aspects of impact of device closure on right heart dimensions and functions, MPA dimensions, reversal of pulmonary hypertension, and comparative analysis with that of surgical closure.

There are only a very few data on isovolumetric acceleration a volume load independent new marker of RV systolic function which is studied in detail in our study.

The impact of device closure on TAPSE has not well been established, and our study provides insight into the decrease of TAPSE, following closure which is well again a hitherto documentation.

CONCLUSION

- We conclude that percutaneous transcatheter device closure is a reliable, safe and cost effective option for ideally selected Ostium Secundum defect patients.

- The maximum beneficial effects on right heart functions, dimensions and remodeling begins immediately after device closure and the continued benefit is observed even at three months

- The beneficial impact on functional capacity, right heart dimensions, functions and hemodynamics are comparable and non inferior to surgical closure patients.

LIMITATIONS OF THE STUDY

1. Estimation of right heart volumes not done.
2. RV diastolic function not assessed.
3. Long term outcome is still under evaluation and hence not included in the study.

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ABBREVIATIONS

- ANOVA, analysis of variance;
- ASD, atrial septal defect
- Qp, pulmonary blood flow;
- Qs, systemic blood flow;
- RA, right atrium;
- RV, right ventricle;
- RVEDD, right ventricular end-diastolic dimension
- IVA = Isovolumic acceleration
- MPI = Myocardial performance index
- LV = Left ventricle
- MPA = Main Pulmonary artery
- PH T = Pulmonary hypertension
- RIMP = Right ventricular index of myocardial performance
- SD = Standard deviation
- TAPSE = Tricuspid annular plane systolic excursion
- TR = Tricuspid regurgitation
- 2D = Two-dimensional

PROFORMA-BASE LINE CHARACTERISTICS

AGE				
SEX				
NYHA CLASS	PRE ASD DEVICE CLOSURE	Post ASD DEVICE CLOSURE (IMMEDIATELY)	Post ASD DEVICE CLOSURE 1-WEEK	Post ASD DEVICE CLOSURE 3-MONTHS
HYPERTENSION				
DM				
ATRIAL SEPTAL DEFECT SIZE				
RIMS				
DEVICE SIZE				
ECG	PRE ASD DEVICE CLOSURE	Post ASD DEVICE CLOSURE (IMMEDIATELY)	Post ASD DEVICE CLOSURE 1-WEEK	Post ASD DEVICE CLOSURE 3-MONTHS

ECHOCARDIOGRAPHIC ASSESSMENT

	PRE ASD DEVICE CLOSURE	Post ASD DEVICE CLOSURE (IMMEDIATELY)	Post ASD DEVICE CLOSURE 1-WEEK	Post ASD DEVICE CLOSURE 3-MONTHS
CHAMBER QUANTIFICATION				
RV BASAL (RV D1)				
RV MID (RV D2)				
RV LONGITUDINAL (RV D3)				
RA MAJOR DIMENSION				
RA MINOR DIMENSION				
MPA SIZE				
RVOT PV/PG				
TAPSE				
MPI				
TR / PG				
IVA				

Parasternal long axis (PLAX), Parasternal short axis (PSAX), Main pulmonary artery (MPA), Tricuspid annular planar systolic excursion (TAPSE), Myocardial performance index (MPI), Fractional area change(FAC), Tricuspid regurgitation peak gradient (TRPG), RT ventricle Isovolumetric acceleration (RV IVA).

Information sheet

- We are conducting a study of the " **Assessment of Right Heart function and dimension following device closure of Atrial Septal Defect** ''at the Department of Cardiology ,Rajiv Gandhi Govt. General Hospital, Chennai. The purpose of this study is to assess right heart function, right atrial and right ventricular dimensions after transcatheter closure of atrial septal defect (ASD) and to investigate factors that may predict magnitude of resolution of right heart enlargement by echocardiography using 2D and tissue doppler imaging .

- The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time. Your decision will not result in any loss of benefits to which you are otherwise entitled.

- The results of the study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of the investigator **Signature of the participant**

PATIENT CONSENT FORM

Study Details : **Assessment of Right Heart function and dimension following device closure of Atrial Septal Defect**

Study Centre : **Department of Cardiology,**
Madras Medical College and
Rajiv Gandhi Government General Hospital,
Chennai - 600 003.

Patient may check (□) these boxes:

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ☐

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ☐

I understand that the investigator of the clinical study, others working on his behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study. ☐

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms. ☐

I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, ECG, Echocardiography appropriate to the clinical diagnosis. ☐

I hereby consent to participate in this study. ☐

Signature / Thumb impression: Place : Date :

Patient Name and Address:

Signature of Investigator: Place :Date :
Study Investigator's Name :

INSTITUTIONAL ETHICS COMMITTEE

MADRAS MEDICAL COLLEGE, CHENNAI – 600 003.

EC Reg. No. ECR /270/Inst/TN/2013

Telephone No. 044 25305301

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CERTIFICATE OF APPROVAL

To .

Dr .J. Cecily Mary Majella,

Post graduate in DM Cardiology,

Department of Cardiology,

Madras Medical College, Chennai 600 003.

Dear Dr. J. Cecily Mary Majella,

The Institutional Ethics Committee of Madras Medical College , reviewed and discussed your application for approval of the"Assessment of Right Heart function and dimension following percutaneous transcatheter device closure of Atrial Septal Defect. 28122013.

The following members of the Ethical Committee were present in the meeting held on 11.12.2013 conducted at Madras Medical College, Chennai – 3.

1. Dr .G.Sivakumar , MS FICS FAIS Chairperson
2. Prof.B.Kalaiselvi , MD
   Vice Principal, MMC, Ch3 Member Secretary
3. Prof.Ramadevi ,
   Director i/c, Institute of Biochemistry, Chennai Member
4. Prof .P.Karkuzhali , MD;
   Prof.Inst .of Pathology, MMC, Ch 3 Member
5. Thiru .S.Govidasamy , BA., BL., Lawyer
6. Tmt .ArmoldSaulina , MA MSW Social Scientist

We approve the proposal to be conducted in its present form.
Sd / Chairman & other Members.

The Institutional Ethics Committee expects to be informed about the progress of the study , and SAE occurring in the course of the study , any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

24/1/14

Member Secretary , Ethics Committee

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" Assessment of Right Heart function and dimensions following device closure of Atrial Septal Defect "

Dissertation submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfillment of the requirements for the award of the degree of

D.M. CARDIOLOGY
BRANCH II – CARDIOLOGY

MADRAS MEDICAL COLLEGE &
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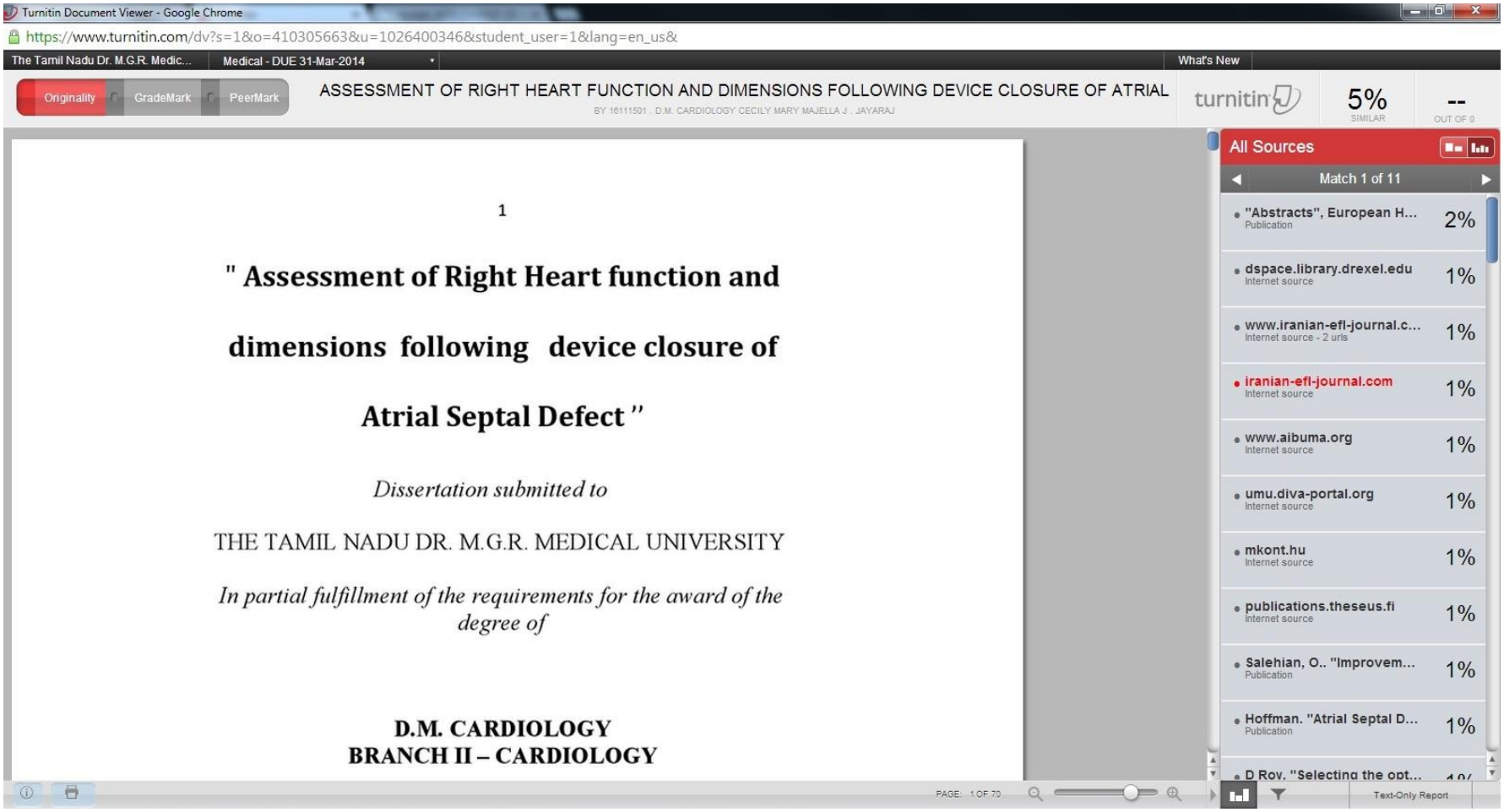
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